

Exhibit A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

FILED
5/31/2019 7:37 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

5259179

This Document Relates To:

JACQUELINE MEDIOUS - SANDERS

Plaintiff,

vs.

ABBOTT LABORATORIES; TAKEDA
PHARMACEUTICALS USA,
INC.; TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA
DEVELOPMENT CENTER AMERICAS,
INC. F/K/A TAKEDA GLOBAL
RESEARCH & DEVELOPMENT CENTER,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED

Defendants.

CASE NO: 2019L006045

Judge

**COMPLAINT WITH JURY
DEMAND ENDORSED HEREON**

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COMES NOW, Plaintiff(s), Jacqueline Medious-Sanders, by and through the undersigned counsel, and brings this Complaint against Abbott Laboratories; Takeda Pharmaceuticals USA, Inc. ("TPUSA"); Takeda Pharmaceuticals America, Inc. ("TPA"); Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. ("TDC Americas"); Takeda Pharmaceutical Company Limited ("TPC"),

hereinafter collectively referred to as “Defendants” and for their Complaint and Jury Demand allege as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants’ defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys’ investigative efforts to date, regarding Defendants’ prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, “the PPI Products” or “PPIs”).

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Prevacid.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

PARTIES, JURISDICTION & VENUE

6. This Complaint is filed on behalf of the Plaintiff and/or Decedent's listed here in, and if applicable, Plaintiff's and/or Decedent's spouses, children, decedents, Estates, Wards, beneficiaries and heirs.

7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this court has in personam jurisdiction over the Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

8. This Court has personal jurisdiction over Defendants, pursuant to, and consistent with, Illinois' long-arm statute (735 ILCS 5/2-209) and the Constitutional requirements of Due Process in that Defendants acting through agents or apparent agents, committed one of more of the following:

- a. Defendants transacted business in the State of Illinois, 735 ILCS 5/2-209(a)(1);
- b. Defendants made or performed a contract or promise substantially connected within this state, 735 ILCS 5/2-209(a)(7);
- c. Defendants do business in and within Illinois, 735 ILCS 5/2-209(b)(4); and;
- d. Requiring Defendants to litigate this claim in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

9. Defendants marked, promoted, and sold PPI Products in this State and in Cook County in particular. Additionally, Defendant Abbot Laboratories has its place of business in

Abbott Park, Illinois along with the following Takeda entities that maintain their place of business in Deerfield, Illinois: Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited (“TPC”). These entities developed, researched, tested, and designed their respective PPI Products within or immediately surrounding Cook County. These ties represent a lasting, significant connection to this venue. Accordingly, venue is appropriate before this Court.

10. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court.

I. PLAINTIFF

11. Plaintiff, Jacqueline Medious-Sanders, resides in Cook county, Illinois and resided in Cook county, Illinois at all times relevant.

- a. Plaintiff, Jacqueline Medious-Sanders ingested the following PPI products sold by the Defendants from at least approximately January 2003 to June 2008:
Prevacid.
- b. As a direct and proximate result of Plaintiff’s use of the PPI(s), Plevacid, Plaintiff has suffered and was treated for Chronic Kidney Disease (“CKD”) in approximately January 2010 with related sequelae.

II. DEFENDANTS

12. Defendant Abbott Laboratories (“Defendant Abbott”) is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, IL. 60064.

13. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

14. Defendant Abbott manufactures and markets Prevacid in the United States.

15. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

16. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

17. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

18. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

19. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

20. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda

Pharmaceuticals USA, Inc.

21. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

22. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

23. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

24. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

25. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

26. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such

agency and employment and with the other Takeda Defendants' actual and implied permission, consent, authorization and approval.

27. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid products.

28. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid products.

29. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

30. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

31. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

32. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

33. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

34. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their

respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

35. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

36. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

37. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

38. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

39. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

40. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

41. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

B. PPI Products Cause Severe Kidney Injuries

42. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

43. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

44. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

45. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology’s Kidney International finding that PPI Product use, by way of AIN, left most patients “with some level of chronic kidney disease.”

46. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, “Systematic review: proton pump inhibitor-associated acute interstitial nephritis.” The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

47. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and

was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, “where PPI-induced AIN is disproportionately present in the database.” Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

48. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen’s Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

49. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

50. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

51. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

52. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

53. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

54. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

55. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

56. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

57. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

58. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

59. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

60. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

61. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ii. PPI-Induced Acute Kidney Injury ("AKI")

62. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

63. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

64. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

65. Currently, the product labeling for PPI Products, both prescription and over-the counter, does not contain any warning regarding the increased risk of AKI.

66. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

iii. PPI-Induced Chronic Kidney Disease ("CKD")

67. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

68. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

69. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

70. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

71. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

72. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

73. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 *Kidney Int*’l 1482 (2017).

74. To date, the labeling for Defendants’ PPI Products lack adequate risk information about CKD.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

75. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

76. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

77. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

78. Because PPI Products work by preventing the acidification of the stomach’s contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies’ acid production increases beyond their pre-PPI treatment levels.

79. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

80. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

81. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

82. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

83. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

D. Safer Alternatives to PPIs

84. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H₂-receptor antagonists (also known as "H₂ Blockers") that were developed in the late 1960s. H₂ Blockers act to prevent the production of

stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H2 Blockers include Zantac, Pepcid and Tagamet. H2 Blockers are not associated with an increased risk of kidney injuries.

85. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

86. Consumers, including Plaintiff, who have used Defendants' PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

E. Injuries Resulting from PPI Products

87. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants' (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

88. As a result of the defective nature of Defendants' PPI Products, persons who ingested Defendants' PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

89. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

90. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

91. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

92. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

93. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants

have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

94. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

95. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

96. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

97. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

98. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

99. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

100. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

101. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

102. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

103. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

104. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

105. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

G. Defendants' Violations of Federal Law

106. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

107. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;
- d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
- e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and

conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;

f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;

n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drugs experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific

papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ESTOPPEL FROM PLEADING AND TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

108. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

109. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not

limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

110. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

111. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

112. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

113. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products

because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

114. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

115. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

116. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

117. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

118. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

119. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

120. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

121. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

CAUSES OF ACTION

COUNT I

STRICT PRODUCT LIABILITY

122. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

123. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including the Plaintiff.

124. At the time of Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

125. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

126. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

127. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiff.

128. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

129. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

130. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary

consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

131. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

132. At the time Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

133. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

134. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

135. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

136. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

137. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

138. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

139. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

140. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

141. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hyper secretion, and the Defendants failed to adequately warn of said risk.

142. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

143. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

144. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

145. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

146. Plaintiff did not misuse or materially alter the PPI Products.

147. Defendants are strictly liable for Plaintiff's injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;

- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

148. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

149. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

150. These defects in Defendants' PPI Products were a substantial factor in causing Plaintiff's injuries.

151. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

152. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants

made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

STRICT PRODUCT LIABILITY –DESIGN DEFECT

153. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

154. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

155. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

156. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

157. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

158. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

159. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

160. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

161. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

162. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

163. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

164. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

165. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and the Plaintiff specifically was not aware of these risks, nor would she expect such risks.

166. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, exceeded the benefits associated with the design or formulation of the PPI Products, or they were more dangerous than an ordinary consumer would expect.

167. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses;
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons;
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons;
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed

that were capable of treating Plaintiff's conditions, while not as prone to cause injury specifically, the risk of kidney injuries.

- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products.

168. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

169. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

170. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

171. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

172. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

173. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community

and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

174. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

175. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

176. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

177. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

178. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

179. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

180. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

181. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

182. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

183. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

184. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff injuries and damages.

185. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe.

186. As a direct and proximate result of Plaintiff use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

187. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damage.

188. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

189. The defective nature of the PPI Products was a substantial factor in causing the Plaintiff's injuries.

190. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

191. Defendants' conduct, as described herein, was extreme and outrageous.

192. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

STRICT PRODUCT LIABILITY – FAILURE TO WARN

193. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the

broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States.

194. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks.

195. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury.

196. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

197. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

198. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

199. The risks of PPI Products were not open and obvious.

200. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

201. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

202. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

203. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

204. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

205. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

206. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

207. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

208. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting

Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

209. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

210. Had Plaintiff and/or Plaintiff's healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

211. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

212. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

213. Plaintiff and Plaintiff's healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

214. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

215. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff,

to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

216. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

217. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

218. Defendants' conduct as described herein was a substantial factor in causing the Plaintiff's injuries.

219. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

220. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

221. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

222. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
NEGLIGENCE

223. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

224. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

225. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or

distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

226. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;

- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
- k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;

- m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
- n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
- o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
- p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
- q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
- r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
- s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
- t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;

- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
- v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
- w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
- x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
- y. Failing to use due care under the circumstances; and
- z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

227. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

228. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

229. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

230. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

231. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm (in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

232. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

233. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff's safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

234. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

235. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain

and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

236. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
NEGLIGENCE PER SE

237. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

238. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

239. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

240. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

241. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

242. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

243. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

244. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

245. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

246. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

247. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

248. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

249. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

250. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

251. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

252. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure and, in some cases, death caused by the use of the PPI Products.

253. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

254. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

255. Defendants are strictly liable for Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

256. As a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and/or death; and economic damages incurred through the treatment for the renal failure and renal injuries and/or death caused by PPI Product use.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
BREACH OF EXPRESS WARRANTY

257. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff plead all Counts of this Complaint in the broadest

sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

258. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

259. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

260. Defendants expressly warranted that their PPI Products were safe and effective to use.

261. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

262. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

263. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

264. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

265. Defendants breached their express warranty in one or more of the following ways:

- a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
- c. Defendants failed to adequately test their PPI Products; and,
- d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

266. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

267. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

268. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

269. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

270. Defendants expressly warranted that PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

271. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

272. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

273. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

274. Plaintiff's injuries (and in some cases death) were the direct and proximate result of Defendants' breach of their express warranty.

275. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

276. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
BREACH OF IMPLIED WARRANTY

277. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff plead all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

278. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

279. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

280. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

281. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

282. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

283. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

284. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

285. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

286. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

287. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

288. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff' injuries.

289. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

290. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
NEGLIGENT MISREPRESENTATION

291. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

292. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

293. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

294. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

295. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and Plaintiff's healthcare providers, as to the health risks and consequences of the use of their PPI Products.

296. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

297. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demand for, as well as the ultimate prescription, purchase and use of their PPI Products.

298. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

299. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

300. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because

such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

301. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

302. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
FRAUD AND FRAUDULENT MISREPRESENTATION

303. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

304. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had

been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

305. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

306. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff, with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

307. These representations made by Defendants were false and misleading.

308. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

309. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

310. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

311. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

312. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

313. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

314. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

315. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
GROSS NEGLIGENCE

316. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States.

317. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

318. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
FRAUDULENT CONCEALMENT

319. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

320. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

321. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

322. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

323. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

324. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

325. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on Defendants' omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

326. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

327. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

328. Defendants also had a duty to disclose material information about serious side effects to consumers such as the Plaintiff.

329. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

330. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

331. Plaintiff's healthcare providers were not provided the necessary information by the Defendants to provide an adequate warning to the Plaintiff.

332. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

333. The PPI Products were improperly marketed to the Plaintiff and/or Plaintiff's healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

334. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

335. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries (and in some cases death).

336. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

337. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

338. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

339. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

340. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

341. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

342. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

343. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous.

344. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and

suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XIII
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

345. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

346. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

347. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, 815 ILCS 505/1.

348. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

349. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and

Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

JURY DEMAND

TAKE NOTICE that the Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: May 31, 2019

Respectfully submitted,

/s/E. Samuel Geisler
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-and-

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ATTORNEYS FOR PLAINTIFF

Civil Action Cover Sheet - Case Initiation

(05/27/16) CCL 0520

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

JACQUELINE MEDIOUS - SANDERS

FILED
5/31/2019 7:37 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

5259179

ABBOTT LABORATORIES; TAKEDA PHARMACEUTICALS USA, INC.; TAKEDA
PHARMACEUTICALS AMERICA, INC.; TAKEDA DEVELOPMENT CENTER AMERICAS,
INC. F/K/A TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.; TAKEDA
PHARMACEUTICAL COMPANY LIMITED

No. 2019L006045

CIVIL ACTION COVER SHEET - CASE INITIATION

A Civil Action Cover Sheet - Case Initiation shall be filed with the complaint in all civil actions. The information contained herein is for administrative purposes only and cannot be introduced into evidence. Please check the box in front of the appropriate case type which best characterizes your action. Only one (1) case type may be checked with this cover sheet.

Jury Demand ☒ Yes ☐ NoPERSONAL INJURY/WRONGFUL DEATH

CASE TYPES:

- ☐ 027 Motor Vehicle
☐ 040 Medical Malpractice
☐ 047 Asbestos
☐ 048 Dram Shop
☒ 049 Product Liability
☐ 051 Construction Injuries
 (including Structural Work Act, Road
 Construction Injuries Act and negligence)
☐ 052 Railroad/FELA
☐ 053 Pediatric Lead Exposure
☐ 061 Other Personal Injury/Wrongful Death
☐ 063 Intentional Tort
☐ 064 Miscellaneous Statutory Action
 (Please Specify Below**)
☐ 065 Premises Liability
☐ 078 Fen-phen/Redux Litigation
☐ 199 Silicone Implant

TAX & MISCELLANEOUS REMEDIES

CASE TYPES:

- ☐ 007 Confessions of Judgment
☐ 008 Replevin
☐ 009 Tax
☐ 015 Condemnation
☐ 017 Detinue
☐ 029 Unemployment Compensation
☐ 031 Foreign Transcript
☐ 036 Administrative Review Action
☐ 085 Petition to Register Foreign Judgment
☐ 099 All Other Extraordinary Remedies

By: E. Samuel Geisler

(Attorney)

(Pro Se)

(FILE STAMP)

COMMERCIAL LITIGATION

CASE TYPES:

- ☐ 002 Breach of Contract
☐ 070 Professional Malpractice
 (other than legal or medical)
☐ 071 Fraud (other than legal or medical)
☐ 072 Consumer Fraud
☐ 073 Breach of Warranty
☐ 074 Statutory Action
 (Please specify below.**)
☐ 075 Other Commercial Litigation
 (Please specify below.**)
☐ 076 Retaliatory Discharge

OTHER ACTIONS

CASE TYPES:

- ☐ 062 Property Damage
☐ 066 Legal Malpractice
☐ 077 Libel/Slander
☐ 079 Petition for Qualified Orders
☐ 084 Petition to Issue Subpoena
☐ 100 Petition for Discovery

**

Primary Email: SGeisler@awkolaw.com

Secondary Email: _____

Tertiary Email: _____

Pro Se Only: ☐ I have read and agree to the terms of the Clerk's Office Electronic Notice Policy and choose to opt in to electronic notice from the Clerk's Office for this case at this email address: _____

DOROTHY BROWN, CLERK OF THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS

FILED
5/31/2019 7:37 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

5259179

2120 - Served
2220 - Not Served
2320 - Served By Mail
2420 - Served By Publication
Summons - Alias Summons

2121 - Served
2221 - Not Served
2321 - Served By Mail
2421 - Served By Publication

(08/01/18) CCG 0001 A

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS

JACQUELINE MEDIOUS - SANDERS

(Name all parties)

v.

ABBOTT LABORATORIES; TAKEDA PHARMACEUTICALS USA, INC.; TAKEDA
PHARMACEUTICALS AMERICA, INC.; TAKEDA DEVELOPMENT CENTER AMERICAS, INC.
F/K/A TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC.; TAKEDA
PHARMACEUTICAL COMPANY LIMITED

Case No. 2019L006045

☒ SUMMONS ☐ ALIAS SUMMONS

To each Defendant:

YOU ARE SUMMONED and required to file an answer to the complaint in this case, a copy of which is hereto attached, or otherwise file your appearance and pay the required fee **within thirty (30) days after service of this Summons**, not counting the day of service. To file your answer or appearance you need access to the internet. Please visit www.cookcountyclerkofcourt.org to initiate this process. Kiosks with internet access are available at all Clerk's Office locations. Please refer to the last page of this document for location information.

If you fail to do so, a judgment by default may be entered against you for the relief requested in the complaint.

To the Officer:

This Summons must be returned by the officer or other person to whom it was given for service, with endorsement of service and fees, if any, immediately after service. If service cannot be made, this Summons shall be returned so endorsed. This Summons may not be served later than thirty (30) days after its date.

Dorothy Brown, Clerk of the Circuit Court of Cook County, Illinois
cookcountyclerkofcourt.org

Summons - Alias Summons

(08/01/18) CCG 0001 B

E-filing is now mandatory for documents in civil cases with limited exemptions. To e-file, you must first create an account with an e-filing service provider. Visit <http://efile.illinoiscourts.gov/service-providers.htm> to learn more and to select a service provider. If you need additional help or have trouble e-filing, visit <http://www.illinoiscourts.gov/FAQ/gethelp.asp>, or talk with your local circuit clerk's office.

Atty. No.: 6305996

Witness: 5/31/2019 7:37 PM DOROTHY BROWN

Atty Name: E. Samuel Geisler

Atty. for: AYI STOCK, WITKIN, KREIS & OVERHOLTZ, PLLC

Address: 17 E. Main Street, Suite 200

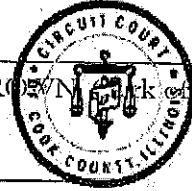
City: Pensacola

State: FL Zip: 32502

Telephone: (850) 202-1010

Primary Email: SGeisler@awkolaw.com

DOROTHY BROWN Clerk of Court



Date of Service: _____
(To be inserted by officer on copy left with
Defendant or other person):

Dorothy Brown, Clerk of the Circuit Court of Cook County, Illinois
cookcountyclerkofcourt.org

FILED DATE: 5/31/2019 7:37 PM 2019L006045

CLERK OF THE CIRCUIT COURT OF COOK COUNTY OFFICE LOCATIONS

- Richard J Daley Center
50 W Washington
Chicago, IL 60602
- District 2 - Skokie
5600 Old Orchard Rd
Skokie, IL 60077
- District 3 - Rolling Meadows
2121 Euclid
Rolling Meadows, IL 60008
- District 4 - Maywood
1500 Maybrook Ave
Maywood, IL 60153
- District 5 - Bridgeview
10220 S 76th Ave
Bridgeview, IL 60455
- District 6 - Markham
16501 S Kedzie Pkwy
Markham, IL 60428
- Domestic Violence Court
555 W Harrison
Chicago, IL 60607
- Juvenile Center Building
2245 W Ogden Ave, Rm 13
Chicago, IL 60602
- Criminal Court Building
2650 S California Ave, Rm 526
Chicago, IL 60608
- Domestic Relations Division
Richard J Daley Center
50 W Washington, Rm 802
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Civil Appeals
Richard J Daley Center
50 W Washington, Rm 801
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Criminal Department
Richard J Daley Center
50 W Washington, Rm 1006
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- County Division
Richard J Daley Center
50 W Washington, Rm 1202
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Probate Division
Richard J Daley Center
50 W Washington, Rm 1202
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Law Division
Richard J Daley Center
50 W Washington, Rm 801
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Traffic Division
Richard J Daley Center
50 W Washington, Lower Level
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm

Daley Center Divisions/Departments

- Civil Division
Richard J Daley Center
50 W Washington, Rm 601
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm
- Chancery Division
Richard J Daley Center
50 W Washington, Rm 802
Chicago, IL 60602
Hours: 8:30 am - 4:30 pm

Dorothy Brown, Clerk of the Circuit Court of Cook County, Illinois
cookcountyclerkofcourt.org

CLERK DIV., RM. 801 DALEY CTR.
CHICAGO, IL. 60602

ID: LD2019L006045 201906070000004
AT: GEISLER EPHRAIM S
TO: SGEISLER@AWKOLAW.COM

* * * * * N O T I C E * * * * *

CASE 19-L-006045

MEDIOUS-SANDERS JACQUELINEV. ABBOTT LABORATORIES
THERE WILL BE A CASE MANAGEMENT CALL OF YOUR CASE ON THURSDAY
THE 1ST DAY OF AUGUST IN ROOM 2202 AT 9:30 A.M. AT THE
DALEY CENTER COURT HOUSE, 50 WEST WASHINGTON STREET, CHICAGO, IL

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

RONALD SUMMERS,

Plaintiff,

v.

TAKEDA PHARMACEUTICALS U.S.A., INC.;
TAKEDA PHARMACEUTICALS AMERICA,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED; TAKEDA
DEVELOPMENT CENTER AMERICAS, INC.,
f/k/a TAKEDA GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC.; TAP
PHARMACEUTICAL PRODUCTS, INC. f/k/a
TAP HOLDINGS, INC.; NOVARTIS
CORPORATION, NOVARTIS
PHARMACEUTICALS CORPORATION;
NOVARTIS VACCINES AND DIAGNOSTICS,
INC.; NOVARTIS INSTITUTES FOR
BIOMEDICAL RESEARCH, INC; NOVARTIS
CONSUMER HEALTH INC. d/b/a GSK;
GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC

Defendants.

Case No. 2019 L 005876



19L6045

AGREED ORDER FOR CONSOLIDATION

This matter coming before the Court on the Parties' Agreed Motion to Consolidate, the Court being fully advised in the premises hereby finds as follows:

1. Plaintiff, Ronald Summers, filed a lawsuit against various manufacturers of prescription proton pump inhibitor medications (PPIs) on May 30, 2019. In his Complaint, Plaintiff alleges personal injuries experienced as a proximate result of the ingestion of PPIs.
2. On May 30 and May 31, 2019, additional Plaintiffs filed Complaints in Cook County alleging similar claims against the Defendants listed above and additional Defendants. These additional cases are identified in **Exhibit A** to this Order.

4316

3. In total, sixty-eight (68) claims are currently pending in Cook County alleging personal injuries experienced as a proximate result of the ingestion of PPIs.
4. Due to the requirement for intensive judicial supervision and management of this mass tort, all parties have agreed to consolidate these matters, and any future related matters, into the first filed case, *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, for pretrial purposes only, pursuant to Paragraph 1.4 (a) of Cook County General Administrative Order 91-4.

IT IS HEREBY ORDERED, by agreement of the parties, as follows:

1. All cases identified on **Exhibit A** are hereby consolidated with *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, for pretrial purposes only. 43/6
2. All future cases filed in the Circuit Court of Cook County, County Department, Law Division, relating to PPIs shall be consolidated for pretrial purposes only with *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X.
3. All future case management conference dates, deadlines, and hearing dates identified in **Exhibit A** are hereby stricken.
4. The case management conference date in the matter of *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, on July 31, 2019 at 9:30 a.m. hereby stands.

Prepared by:

TUCKER ELLIS LLP
233 South Wacker Drive
Suite 6950
Chicago, Illinois 60606
Firm ID: 59175

Entered: 

The Honorable James P. Flannery Jr.

1505

JUDGE JAMES P. FLANNERY

JUL 29 2019

Circuit Court-1505

EXHIBIT A

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005876	Judge Brendan A. O' Brien	X	7/31/2019 at 9:30 a.m.- Date to Stand
Beverly A. Miller v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005878	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Connie Hoffman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005886	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Dawn Funches v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005904	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Clay Luzena v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005909	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.
Anderson Blair v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005942	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Velma McChrison v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005943	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
William Tracy v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005946	Judge Brendan A. O' Brien	X	7/31/2019 at 9:30 a.m.
Al Ware v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005950	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
William Barden v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005952	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Marla Davis v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005953	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Mark Allen Bramlet v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005954	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Tawana Bond v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005958	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Francis M. Rozich v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005961	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Dennis Carroll v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005962	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Tammy Chasse v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005971	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Rebecca Swanigan v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005973	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Alfreda Swope v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005974	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Faustino P Pacheco v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005975	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Kathy Moore v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005978	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Daniel Topel v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005979	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Sharon Cielocha v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005982	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
James Penington v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005983	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Yolanda Taylor v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005984	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Barry Miller v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005985	Judge Kathy M. Flanagan		8/1/2019 at 9:00 a.m.
Dorothy Freeman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005987	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
James Climons v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005988	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Karolin Pierson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005991	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Pamela Powers v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005993	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.
Michelle Cooper v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005994	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Debbie Jackson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005995	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Holly Wade v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005999	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
George Davis v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006000	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Ronald Ranger v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006001	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Richard Devriendt v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006004	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Harold Dewese v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006006	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
John Ebler Sr., v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006008	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Sammie Evans v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006010	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Gale Gipson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006011	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Sheila Young v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006013	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Queen Johnson-Poellinetz v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006014	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Beverly Boehm v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006016	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Allen Green v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006017	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Randi Burgdorf v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006021	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Wanda Klein v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006023	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.
James Irons v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006024	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Antoinette Stewart v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006025	Judge Ronald F. Bartkowicz	J	8/16/2019 at 9:30 a.m.
Carolyn Lind v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006030	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Robert Lovall v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006031	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Jackie Isley v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006032	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Kelvin Smith v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006033	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Elizabeth Gregory v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006035	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Jacqueline Iverson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006038	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Loretta Jones v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006040	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Lawrence Schumaker v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006041	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Chavetta Dye v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006042	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Melanthia Jones v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006043	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Jacqueline Medious-Sanders v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006045	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Rhonda Harmon v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006047	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Nicole Bush-Sanders v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006049	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Kimberly Freely v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006058	Judge Kathy M. Flanagan		8/1/2019 at 9:00 a.m.
Sharon Gammon Kossman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006059	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
James Sladek v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006060	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Robert Reece v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006061	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Edward O'Connor v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006062	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Alverner Smith v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006067	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:30 a.m.
Pearline Ballard v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006069	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Harold Benoit v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006071	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION



RONALD SUMMERS,

Plaintiff,

v.

TAKEDA PHARMACEUTICALS U.S.A., INC.;
TAKEDA PHARMACEUTICALS AMERICA,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED; TAKEDA
DEVELOPMENT CENTER AMERICAS, INC.,
f/k/a TAKEDA GLOBAL RESEARCH &
DEVELOPMENT CENTER, INC.; TAP
PHARMACEUTICAL PRODUCTS, INC. f/k/a
TAP HOLDINGS, INC.; NOVARTIS
CORPORATION, NOVARTIS
PHARMACEUTICALS CORPORATION;
NOVARTIS VACCINES AND DIAGNOSTICS,
INC.; NOVARTIS INSTITUTES FOR
BIOMEDICAL RESEARCH, INC; NOVARTIS
CONSUMER HEALTH INC. d/b/a GSK;
GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC

Defendants.

Case No. 2019 L 005876

19L0045

AGREED ORDER FOR CONSOLIDATION

This matter coming before the Court on the Parties' Agreed Motion to Consolidate, the Court being fully advised in the premises hereby finds as follows:

1. Plaintiff, Ronald Summers, filed a lawsuit against various manufacturers of prescription proton pump inhibitor medications (PPIs) on May 30, 2019. In his Complaint, Plaintiff alleges personal injuries experienced as a proximate result of the ingestion of PPIs.
2. On May 30 and May 31, 2019, additional Plaintiffs filed Complaints in Cook County alleging similar claims against the Defendants listed above and additional Defendants. These additional cases are identified in **Exhibit A** to this Order.

3. In total, sixty-eight (68) claims are currently pending in Cook County alleging personal injuries experienced as a proximate result of the ingestion of PPIs.

4. Due to the requirement for intensive judicial supervision and management of this mass tort, all parties have agreed to consolidate these matters, and any future related matters, into the first filed case, *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, for pretrial purposes only, pursuant to Paragraph 1.4 (a) of Cook County General Administrative Order 91-4.

IT IS HEREBY ORDERED, by agreement of the parties, as follows:

1. All cases identified on **Exhibit A** are hereby consolidated with *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, for pretrial purposes only. 4216
8213
2175
2. All future cases filed in the Circuit Court of Cook County, County Department, Law Division, relating to PPIs shall be consolidated for pretrial purposes only with *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X. 4619
4335
4331
3. All future case management conference dates, deadlines, and hearing dates identified in **Exhibit A** are hereby stricken.
4. The case management conference date in the matter of *Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.*, case no. 2019-L-005876, pending before the Honorable Brendan A. O' Brien, Calendar X, on July 31, 2019 at 9:30 a.m. hereby stands.

Prepared by:

TUCKER ELLIS LLP
233 South Wacker Drive
Suite 6950
Chicago, Illinois 60606
Firm ID: 59175

Entered: 

The Honorable James P. Flannery Jr.

1505

JUDGE JAMES P. FLANNERY

JUL 29 2019

Circuit Court-1505

EXHIBIT A

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Ronald Summers v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005876	Judge Brendan A. O' Brien	X	7/31/2019 at 9:30 a.m.- Date to Stand
Beverly A. Miller v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005878	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Connie Hoffman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005886	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Dawn Funches v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005904	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Clay Luzena v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005909	Judge James N. O' Hara	A	7/31/2019 at 10:00 a.m.
Anderson Blair v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005942	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Velma McChriston v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005943	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
William Tracy v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005946	Judge Brendan A. O' Brien	X	7/31/2019 at 9:30 a.m.
Al Ware v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005950	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
William Barden v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005952	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Marla Davis v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005953	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Mark Allen Bramlet v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005954	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Tawana Bond v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005958	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Francis M. Rozich v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005961	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Dennis Carroll v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005962	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Tammy Chasse v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005971	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Rebecca Swanigan v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005973	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Alfreda Swope v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005974	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Faustino P Pacheco v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005975	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Kathy Moore v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005978	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Daniel Topel v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005979	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Sharon Cielocha v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005982	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
James Penington v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005983	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Yolanda Taylor v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005984	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Barry Miller v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005985	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Dorothy Freeman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005987	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
James Climons v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005988	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Karolin Pierson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005991	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Pamela Powers v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005993	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.
Michelle Cooper v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005994	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Debbie Jackson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005995	Judge Melissa A. Durkin	C	7/30/2019 at 9:30 a.m.
Holly Wade v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L005999	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
George Davis v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006000	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Ronald Ranger v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006001	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Richard Devriendt v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006004	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Harold Dewese v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006006	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
John Ebler Sr. v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006008	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Sammie Evans v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006010	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Gale Gipson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006011	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Sheila Young v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006013	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Queen Johnson-Poellinetz v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006014	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Beverly Boehm v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006016	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.
Allen Green v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006017	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Randi Burgdorf v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006021	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Wanda Klein v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006023	Judge James N. O'Hara	A	7/31/2019 at 10:00 a.m.
James Irons v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006024	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Antoinette Stewart v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006025	Judge Ronald F. Bartkowicz	J	8/16/2019 at 9:30 a.m.
Carolyn Lind v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006030	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Robert Lovall v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006031	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Jackie Isley v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006032	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Kelvin Smith v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006033	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Elizabeth Gregory v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006035	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Jacqueline Iverson v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006038	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Loretta Jones v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006040	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Lawrence Schumaker v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006041	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Chavetta Dye v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006042	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Melanthia Jones v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006043	Judge Allen P. Walker	Z	7/30/2019 at 9:45 a.m.
Jacqueline Medious-Sanders v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006045	Judge Daniel T. Gillespie	B	8/1/2019 at 9:30 a.m.
Rhonda Harmon v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006047	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:00 a.m.

Case Name	Case No.	Judge Name	Calendar	CMC/Hearing Date
Nicole Bush-Sanders v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006049	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Kimberly Freely v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006058	Judge Kathy M. Flanagan	E	8/1/2019 at 9:00 a.m.
Sharon Gammon Kossman v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006059	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
James Sladek v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006060	Judge Christopher E. Lawler	R	7/31/2019 at 9:30 a.m.
Robert Reece v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006061	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.
Edward O'Connor v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006062	Judge John H. Ehrlich	H	8/1/2019 at 9:00 a.m.
Alverner Smith v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006067	Judge Patricia O'Brien Sheahan	D	7/30/2019 at 10:30 a.m.
Pearline Ballard v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006069	Judge Moira S. Johnson	F	7/31/2019 at 9:30 a.m.
Harold Benoit v. Takeda Pharmaceuticals U.S.A., Inc., et al.	2019L006071	Judge Brendan A. O'Brien	X	7/31/2019 at 9:30 a.m.

IN THE CIRCUIT COURT OF THE 13th JUDICIAL CIRCUIT IN AND FOR COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT-LAW DIVISION

Rev. 3/18

MEDIOUS

Plaintiffs

Abbott

Defendants

NO: 19C-6055 6045Motion Call: "B" Time: 9:30 Line #: 1212

2005 Trial Date: _____

****CASE MANAGEMENT ORDER******** (Please check off all pertinent paragraphs and circle proper party name) ****

- (4231) 1. Written, 213(f)(1), (f)(2) and 214 discovery to be issued by _____ or deemed waived;
- (4296) 2. Written, 213(f)(1), (f)(2) and 214 discovery to be answered by _____;
- (4218) 3. Party depositions, fact, 213(f)(1) and/or (2) depositions to be completed by _____;
- (4297) 4. Plaintiff to send list & addresses of treaters and HIPAA order to Defendant(s) by _____;
- (4288) 5. Subpoenas for treating physicians' records/deps to be issued by _____ or deemed waived;
- (4218) 6. Treating physicians depositions to be completed by _____;
- (4231) 7. All dispositive motions shall be filed no later than _____;
- (4296) 8. All SCR 215 & 216 discovery completed by _____;
- (4206) 9. (Plaintiff) - (Defendant) - (Add. Party) shall answer 213 (f)(3) Interrogatories by _____;
- (4218) 10. Plaintiff's 213(f)(3) witnesses' depositions to be completed by _____;
- (4218) 11. Defendant's 213(f)(3) witnesses' depositions to be completed by _____;
- (4218) 12. Add. party's 213(f)(3) witnesses' depositions to be completed by _____;
- (4295) 13. All fact discovery, SCR 213(f)(1), (f)(2), 215(a) and 216 discovery is closed. (Circle all applicable)
- (4619) 14. The matter is continued for subsequent Case Management Conference on _____ at _____ AM/PM in Room 2202 for:
- | | | |
|-----------------------------|-------------------------------------|---------------------------------|
| (A) <u>Proper Service</u> | (B) <u>Appearance of Defendants</u> | (C) <u>Case Value</u> |
| (D) <u>Pleadings Status</u> | (E) <u>Discovery Status</u> | (F) <u>Pre-Trial/Settlement</u> |
| (G) <u>Mediation Status</u> | (H) <u>Trial Certification</u> | (I) <u>Other</u> |

C H X

- (4005) 15. Case is DWP'd. (4040) The case is voluntarily dismissed pursuant to 735 ILCS 5/2-1009.
- (4331) 16. Case stricken from CMC Call (4284) Motion Stricken or Withdrawn from Call (4330) Case stricken from Motion Call.

NAME: _____

ADDRESS: _____

PHONE: _____

ATTY ID#: _____

ATTY FOR PARTY: _____

NOTICE: _____

★ COPIES OF ALL PRIOR CMC ORDERS MUST BE BROUGHT TO ALL CMC COURT DATES.

★ FAILURE OF ANY PARTY TO COMPLY WITH THIS CMC ORDER WILL BE A BASIS FOR SCR 219(C) SANCTIONS. FAILURE OF ANY PARTY TO ENFORCE THIS CMC ORDER WILL CONSTITUTE A WAIVER OF SUCH DISCOVERY BY THAT PARTY.

JUDGE

NO.

JUDGE Karen C. ... 2036

AUG 01 2020

CLERK OF
DEPUTY CLERK

ID: LD2019L006045 20200415000010
AT: GEISLER EPHRAIM S
TO: SGEISLER@AUKOLAW.COM

* * * * * N O T I C E * * * * *

CASE 19-L-006045

MEDIOUS-SANDERS JACQUELINV.

ABBOTT LABORATORIES

BY AMENDED GENERAL ADMINISTRATIVE ORDER OF THE COOK COUNTY
CIRCUIT COURT ADDRESSING COVID-19 PRECAUTIONS, YOUR CASE IN THE
CIRCUIT COURT OF COOK COUNTY HAS BEEN RESCHEDULED TO MONDAY,
THE 6TH DAY OF JULY 2020, AT 10:45 A.M., IN ROOM 2205.

THIS REPLACES ANY PREVIOUS COVID-19 NOTICE.

ID: LD2019L006045 20200623000011
AT: GEISLER EPHRAIM S
TO: SGEISLER@AWKOLAW.COM

* * * * * N O T I C E * * * * *

CASE 19-L-006045

MEDIOUS-SANDERS JACQUELINV.

ABBOTT LABORATORIES

BY AMENDED GENERAL ADMINISTRATIVE ORDER OF THE COOK COUNTY
CIRCUIT COURT ADDRESSING COVID-19 PRECAUTIONS, YOUR CASE IN THE
CIRCUIT COURT OF COOK COUNTY HAS BEEN RESCHEDULED TO THURSDAY,
THE 4TH DAY OF FEBRUARY 2021, AT 10:30 A.M., IN ROOM 2205.

THIS REPLACES ANY PREVIOUS COVID-19 NOTICE.

MASKS/COVERINGS ARE REQUIRED IN THE DALEY CENTER, ALL
COURTHOUSE BUILDINGS, AND ALL OTHER CLERKS OFFICE LOCATIONS.

FILED
7/29/2019 4:02 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

5960205

**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION**

This Document Relates To:

JACQUELINE MEDIOUS-SANDERS

Plaintiff,

vs.

ABBOTT LABORATORIES;
TAKEDA PHARMACEUTICALS USA, INC.;
TAKEDA PHARMACEUTICALS AMERICA,
INC.; TAKEDA DEVELOPMENT CENTER
AMERICAS, INC. F/K/A TAKEDA GLOBAL
RESEARCH & DEVELOPMENT CENTER,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED

Defendants.

CASE NO: 2019-L-006045

Judge

**ANSWER AND SEPARATE OR
AFFIRMATIVE DEFENSES OF
ABBOTT LABORATORIES**

**JURY DEMAND ENDORSED
HEREON**

COMES NOW, Abbott Laboratories, by and through its attorneys, answers Plaintiff's
Complaint as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory and punitive damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts to date, regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

ANSWER: Abbott admits that Plaintiff seeks damages and other relief against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPIs.” Abbott denies that Plaintiff is entitled to judgment, damages, or relief of any kind and further denies the remaining allegations of paragraph 1.

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

ANSWER: Abbott states that the allegations of paragraph 2 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

3. As more particularly set forth herein, the plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use.

ANSWER: Abbott denies the allegations of paragraph 3.

4. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Prevacid.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. To the extent a response is required, Abbott admits that Plaintiff has brought a personal injury action against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPI’s.” Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott denies that it is liable to Plaintiff for any claims in any personal injury action and further denies any remaining allegations of paragraph 4 that are

directed to it.

5. PPI Products are used to suppress the production of acid in order to reduce the risk of duodenal ulcer recurrence and NSAID-associated gastric ulcers as well as to treat gastroesophageal reflux disease (“GERD”) and certain pathological hypersecretory conditions including Zollinger-Ellison syndrome.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Because the remaining allegations of paragraph 5 are vague and ambiguous as applied to Abbott, they are denied.

PARTIES, JURISDICTION & VENUE

6. This Complaint is filed on behalf of the Plaintiff and/or Decedent’s listed here in, and if applicable, Plaintiff’s and/or Decedent’s spouses, children, decedents, Estates, Wards, beneficiaries and heirs.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent a response is required, Abbott admits that Plaintiff has brought a personal injury action against the named defendants. Abbott denies any remaining allegations of paragraph 6 that are directed to it.

7. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this court has in personam jurisdiction over the Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States and that its

principal place of business is in the State of Illinois. Abbott denies the remaining allegations of paragraph 7.

8. This Court has personal jurisdiction over Defendants, pursuant to, and consistent with, Illinois' long-arm statute (735 ILCS 5/2-209) and the Constitutional requirements of Due Process in that Defendants acting through agents or apparent agents, committed one of more of the following:

- a. Defendants transacted business in the State of Illinois, 735 ILCS 5/2-209(a)(1);
- b. Defendants made or performed a contract or promise substantially connected within this state, 735 ILCS 5/2-209(a)(7);
- c. Defendants do business in and within Illinois, 735 ILCS 5/2-209(b)(4); and;
- d. Requiring Defendants to litigate this claim in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States and that its principal place of business is in the State of Illinois. Abbott denies the remaining allegations of paragraph 8, including all subparts.

9. Defendants marked, promoted, and sold PPI Products in this State and in Cook County in particular. Additionally, Defendant Abbot Laboratories has its place of business in Abbott Park, Illinois along with the following Takeda entities that maintain their place of business in Deerfield, Illinois: Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited ("TPC"). These entities developed, researched, tested, and designed their respective PPI Products within or immediately surrounding Cook County. These ties represent a lasting, significant connection to this venue. Accordingly, venue is appropriate before this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States

and that its principal place of business is in the State of Illinois. Abbott denies the remaining allegations of paragraph 9.

10. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to seek an amount in controversy that exceeds the jurisdictional limits of this Court. Abbott denies the remaining allegations of paragraph 10.

I. PLAINTIFF

11. Plaintiff, Jacqueline Medious-Sanders, resides in Cook county, Illinois and resided in Cook county, Illinois at all times relevant.

- a. Plaintiff, Jacqueline Medious-Sanders ingested the following PPI products sold by the Defendants from at least approximately January 2003 to June 2008: Prevacid.
- b. As a direct and proximate result of Plaintiff's use of the PPI(s), Prevacid, Plaintiff has suffered and was treated for Chronic Kidney Disease ("CKD") in approximately January 2010 with related sequelae.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff, and therefore denies them. Abbott denies the remaining allegations of paragraph 11, including all subparts.

II. DEFENDANTS

12. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, IL. 60064.

ANSWER: Abbott admits the allegations of paragraph 12.

13. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

ANSWER: Abbott admits that, at various times in the past, Abbott researched, tested,

packaged, marketed and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott specifically denies that it manufactured Prevacid® and further denies the remaining allegations of paragraph 13.

14. Defendant Abbott manufactures and markets Prevacid in the United States.

ANSWER: Abbott admits that, at various times in the past, Abbott marketed and/or promoted Prevacid® in the United States but specifically denies that it manufactured Prevacid®, and denies any remaining allegations of paragraph 14.

15. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

ANSWER: Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in each of the States and the District of Columbia. Abbott denies the remaining allegations of paragraph 15.

16. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

ANSWER: Abbott admits that it has received revenue from the sale of Prevacid® in the United States. Abbott states that the phrase “substantial revenue” is vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Abbott denies any remaining or inconsistent allegations of paragraph 16.

17. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

ANSWER: Abbott states that the phrases “its acts,” “consequence,” and “substantial revenue” are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same,

and therefore denies them. Abbott denies the remaining allegations of paragraph 17.

18. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 18, and therefore denies them.

19. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 19, and therefore denies them.

20. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 20, and therefore denies them.

21. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 21, and therefore denies them.

22. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 22, and therefore denies them.

23. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 23, and therefore denies them.

24. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 24, and therefore denies them.

25. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

ANSWER: Abbott states that the allegations of this paragraph do not require a response.

If a response is required, Abbott admits that Plaintiff refers to Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Takeda Pharmaceutical Company Limited as “Takeda Defendants.” Abbott denies any remaining allegations of paragraph 25.

26. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Prevacid products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27, and therefore denies them.

28. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 29, and therefore denies them.

30. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30, and therefore denies them.

31. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31, and therefore denies them.

32. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 32, and therefore denies them.

33. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial

revenue from interstate commerce in each of the States and Territories of the United States related to PPI Products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 33, and therefore denies them.

34. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 34 at this time, and therefore denies them. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

35. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 35 at this time, because jurisdictional issues are dependent on the facts of each case. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

FACTUAL ALLEGATIONS

36. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 36 at this time, and therefore denies them.

37. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action is outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 37 at this time, and therefore denies them.

38. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

ANSWER: Abbott states that the allegations of this paragraph are vague and ambiguous as written. As such, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 38, and therefore denies them.

39. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 39, and therefore denies them.

40. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 40, and therefore denies them.

41. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 41, and therefore denies them.

42. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

ANSWER: Abbott admits that Dr. Stephen Ruffenach and other researchers from the University of Arizona Health Sciences Center published an article in the American Journal of Medicine in 1992 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 42.

43. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

ANSWER: Abbott states that the allegations of paragraph 43 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

44. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

ANSWER: Abbott states that the allegations of paragraph 44 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

45. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

ANSWER: Abbott admits that researchers from the Yale School of Medicine published an article in the International Society of Nephrology's Kidney International in 2006 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 45.

46. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

ANSWER: Abbott admits that Dr. F. Sierra and others published an article in the Journal of Alimentary Pharmacology and Therapeutics in 2007 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 46.

47. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, "where PPI-induced AIN is disproportionately present in the database." Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

ANSWER: Abbott states that Dr. Harmark and others published an article in the British Journal of Clinical Pharmacology in 2007 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 47.

48. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

ANSWER: Abbott admits, on information and belief, that on August 23, 2011, Public Citizen filed a petition with the FDA requesting that additional warnings be added to the labeling of PPI products. Abbott denies the validity of this citizen's petition and further denies the

remaining allegations of paragraph 48.

49. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

ANSWER: Abbott admits, on information and belief, that the Public Citizen petition filed with the FDA on August 23, 2011 stated that “[i]nformation regarding the potential for drug-induced acute interstitial nephritis, seen in at least 60 case reports, should be included in the appropriate section. There is currently no detailed risk information on any PPI for this adverse effect.” Abbott denies the validity of this citizen’s petition and further denies the remaining allegations of paragraph 49.

50. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen’s petition by concluding that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 50.

51. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen’s petition by stating that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 51.

52. In December of 2014, all labels for prescription PPI Products were required to

include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 52, and therefore denies them.

53. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

ANSWER: Abbott states that the allegations of paragraph 53 do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted any "over-the counter PPI Products" as alleged and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to the identification of the products at issue in this paragraph. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

54. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

ANSWER: Abbott denies the allegations of paragraph 54.

55. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

ANSWER: Abbott denies the allegations of paragraph 55.

56. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

ANSWER: Abbott denies that that the mechanism by which drugs may cause AIN has

been established. Abbott denies any remaining or inconsistent allegations of paragraph 56.

57. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

ANSWER: Abbott admits that not every patient diagnosed with AIN presents with a fever.

Abbott denies any remaining or inconsistent allegations of paragraph 57.

58. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

ANSWER: Abbott admits that the publications referenced in this paragraph are in the published literature and state that these publications speak for themselves. Abbott denies that the mechanism by which drugs may cause AIN has been established and further denies any remaining or inconsistent allegations of paragraph 58.

59. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott lacks knowledge or information sufficient to form a belief as to the truth the remaining allegations of paragraph 59, and therefore denies them.

60. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure. Abbott lacks knowledge or information

sufficient to form a belief as to the remaining allegations of paragraph 60, and therefore denies them.

61. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 61, and therefore denies them.

62. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

ANSWER: Abbott denies that Prevacid® causes acute kidney injury or renal failure. Abbott admits that Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly. Abbott denies any remaining allegations of paragraph 62.

63. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

ANSWER: Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and denies the allegations of paragraph 63.

64. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

ANSWER: Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them. Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies any remaining allegations of paragraph 64.

65. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

ANSWER: Abbott admits, on information and belief, that Prevacid®'s product labeling does not explicitly reference AKI as defined in the Plaintiff's Complaint. Abbott further denies any remaining or inconsistent allegations of paragraph 65.

66. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

ANSWER: Abbott denies the allegations of paragraph 66.

67. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

ANSWER: Abbott admits that chronic kidney disease is the gradual loss of kidney function. Abbott denies that Prevacid® causes chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 67.

68. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

ANSWER: Abbott admits that chronic kidney disease can, but does not always, lead to the development of end stage renal disease. Abbott denies that Prevacid® cause chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 68.

69. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

ANSWER: Abbott admits that a study was published in the Journal of the American Medical Association in January 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 69.

70. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

ANSWER: Abbott admits that a study was published in the Journal of the American Society of Nephrology in February 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease, progression of kidney disease, or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 70.

71. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

ANSWER: Abbott admits that a study was published in the Journal of Nephrology in April 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 71.

72. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

ANSWER: Abbott denies the allegations characterizing chronic kidney disease in paragraph 72 and further denies that Prevacid® causes chronic kidney disease or end stage renal failure.

73. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton

Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int'l 1482 (2017).

ANSWER: Abbott admits that a study was published in the Kidney International in 2017 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 73.

74. To date, the labeling for Defendants' PPI Products lack adequate risk information about CKD.

ANSWER: Abbott denies the allegations of paragraph 74.

75. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

ANSWER: Abbott denies the allegations of paragraph 75.

76. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as "rebound acid hypersecretion" and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 76.

77. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted "omeprazole/Prilosec" and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to "phenomenon." Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 77, and therefore denies them.

78. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases

beyond their pre-PPI treatment levels.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 78.

79. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

ANSWER: Abbott denies the allegations of paragraph 79.

80. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

ANSWER: Abbott denies the allegations of paragraph 80.

81. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

ANSWER: Abbott states that the term "studies" is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth of the allegations of paragraph 81 and therefore denies them.

82. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 82.

83. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

ANSWER: Abbott denies the allegations of paragraph 83.

84. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

a. The use of over-the-counter calcium carbonate tablets that have been available

- since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H2-receptor antagonists (also known as “H2 Blockers”) that were developed in the late 1960s. H2 Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H2 Blockers include Zantac, Pepcid and Tagamet. H2 Blockers are not associated with an increased risk of kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 84, including all subparts.

85. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

ANSWER: Abbott admits that Dr. Marks published an article in The Pharmaceutical Journal in 2016 and states that the article speaks for itself. Abbott denies any remaining allegations of paragraph 85.

86. Consumers, including Plaintiff, who have used Defendants’ PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 86.

87. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants’ (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

ANSWER: Abbott denies the allegations of paragraph 87.

88. As a result of the defective nature of Defendants’ PPI Products, persons who ingested Defendants’ PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

ANSWER: Abbott denies the allegations of paragraph 88.

89. Consumers, including Plaintiff, who have used Defendants’ PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 89.

90. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 90.

91. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 91.

92. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

ANSWER: Abbott denies the allegations of paragraph 92.

93. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 93.

94. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

ANSWER: Abbott denies the allegations of paragraph 94.

95. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

ANSWER: Abbott denies the allegations of paragraph 95.

96. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no answer is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 96.

97. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

ANSWER: Abbott states that the allegations of paragraph 97 constitute legal conclusions to which no answer is required. To the extent that the allegations are construed as factual allegations directed to Abbott, they are denied.

98. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

ANSWER: To the extent that the allegations of paragraph 98 are directed to Abbott, Abbott denies them.

99. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

ANSWER: To the extent that the allegations of paragraph 99 are directed to Abbott, Abbott denies them.

100. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

ANSWER: To the extent that the allegations of paragraph 100 are directed to Abbott, Abbott denies them.

101. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

ANSWER: Abbott denies the allegations of paragraph 101.

102. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

ANSWER: To the extent that the allegations of paragraph 102 are directed to Abbott, Abbott denies them.

103. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

ANSWER: To the extent that the allegations of paragraph 103 are directed to Abbott, Abbott denies them.

104. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

ANSWER: To the extent that the allegations of paragraph 104 are directed to Abbott, Abbott denies them.

105. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved

product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 105.

106. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

ANSWER: Abbott states that the allegations of paragraph 106 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

107. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;
- d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
- e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;
- f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;
- g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;
- h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests

needed for monitoring of patients who took their respective prescription PPI Products;

- i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;
- j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;
- k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;
- l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;
- m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;
- n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;
- o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;
- p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;
- q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;
- r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;
- s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drugs experience report;
- t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;
- u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;
- v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of

- the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;
- w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as “15-day Alert report,” or “15-day Alert report follow-up”;
 - x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant’s PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;
 - y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and
 - z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.
 - aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ANSWER: Abbott states that the allegations of paragraph 107 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, Abbott denies them, including all subparts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

108. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff’s resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

109. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited

to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert tolling of relevant statutes of limitations, but denies that Plaintiff is entitled to such tolling. Abbott denies any remaining allegations of paragraph 109.

110. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert application of the discovery rule, but denies that Plaintiff is entitled to such application. Abbott denies any remaining allegations of paragraph 110.

111. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 111 are construed as factual allegations directed to Abbott, Abbott denies them.

112. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and

could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 112 are construed as factual allegations directed to Abbott, Abbott denies them.

113. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 113.

114. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

ANSWER: To the extent that the allegations of paragraph 114 are directed to Abbott, Abbott denies them.

115. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

ANSWER: To the extent that the allegations of paragraph 115 are directed to Abbott, Abbott denies them.

116. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers

reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

ANSWER: To the extent that the allegations of paragraph 116 are directed to Abbott, Abbott denies them.

117. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products and medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 117.

118. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products or medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 118.

119. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's medical condition, and therefore denies them. Abbott denies any remaining allegations of paragraph 119.

120. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

ANSWER: To the extent the allegations of paragraph 120 are directed to Abbott, Abbott

denies them.

121. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products or medical condition, and therefore denies them. Abbott denies any remaining allegations of paragraph 121.

CAUSES OF ACTION

COUNT I

STRICT PRODUCT LIABILITY

122. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

123. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 123 and specifically denies that it manufactured Prevacid® and denies that Prevacid® was defective or unreasonably dangerous.

124. At the time of Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 124 and specifically denies that Prevacid® was defective or unreasonably dangerous.

125. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

ANSWER: Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 125, and specifically denies that it manufactured Prevacid®.

126. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

ANSWER: Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® "did reach" users without substantial change in the condition in which it was distributed, and therefore denies them. Abbott denies the remaining allegations of paragraph 126.

127. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiff.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 127, and specifically denies that it manufactured Prevacid®.

128. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 128, and specifically denies that Prevacid® is or was defective.

129. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

ANSWER: Abbott denies the allegations of paragraph 129, and specifically denies that Prevacid® is or was defective or unsafe.

130. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 130, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

131. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

ANSWER: Abbott denies the allegations of paragraph 131, and specifically denies that Prevacid® is or was defective, inherently dangerous, or unsafe.

132. At the time Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 132, and therefore denies them.

133. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 133.

134. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute

legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining or inconsistent allegations of paragraph 134.

135. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

ANSWER: Abbott denies the allegations of paragraph 135.

136. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

ANSWER: Abbott denies the allegations of paragraph 136, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

137. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

ANSWER: Abbott denies the allegations of paragraph 137, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

138. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 138.

139. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

ANSWER: Abbott denies the allegations of paragraph 139, and specifically denies that Prevacid® is or was defective or dangerous.

140. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to

adequately warn of said risk.

ANSWER: Abbott denies the allegations of paragraph 140.

141. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

ANSWER: Abbott denies the allegations of paragraph 141, and specifically denies that Prevacid® is or was defective or dangerous.

142. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

ANSWER: Abbott denies the allegations of paragraph 142, and specifically denies that Prevacid® is or was defective or dangerous.

143. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

ANSWER: Abbott denies the allegations of paragraph 143, and specifically denies that Prevacid® is or was defective or dangerous.

144. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 144, and specifically denies that Prevacid® is or was defective.

145. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 145, and therefore denies them.

146. Plaintiff did not misuse or materially alter the PPI Products.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 146, and therefore denies them.

147. Defendants are strictly liable for Plaintiff's [sic] injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 147, including all subparts, and specifically denies that Prevacid® is or was defective or dangerous.

148. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

ANSWER: Abbott denies the allegations of paragraph 148.

149. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Abbott denies the allegations of paragraph 149.

150. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 150.

151. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 151.

152. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 152.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT II

STRICT PRODUCT LIABILITY – DESIGN DEFECT

153. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

154. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

ANSWER: Abbott denies the allegations of paragraph 154, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

155. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 155.

156. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

ANSWER: Abbott denies the allegations of paragraph 156.

157. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 157, and therefore denies them.

158. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

ANSWER: Abbott denies the allegations of paragraph 158.

159. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

ANSWER: Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® "did reach" intended consumers, including Plaintiff, without substantial change in the condition in which it was distributed, and therefore denies them. Abbott specifically denies that it was a manufacturer of Prevacid®, and further denies any remaining allegations of paragraph 159.

160. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

ANSWER: Abbott denies the allegations of paragraph 160.

161. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable

to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 161, and specifically denies that Prevacid® is or was defective or dangerous.

162. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

ANSWER: Abbott denies the allegations of paragraph 162, and specifically denies that Prevacid® is or was defective or unsafe.

163. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 163.

164. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

ANSWER: Abbott denies the allegations of paragraph 164.

165. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and the Plaintiff specifically was not aware of these risks, nor would she expect such risks.

ANSWER: Abbott denies the allegations of paragraph 165.

166. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, exceeded the benefits associated with the design or formulation of the PPI Products, or they were more dangerous than an ordinary consumer would expect.

ANSWER: Abbott denies the allegations of paragraph 166.

167. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses;

- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons;
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons;
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury specifically, the risk of kidney injuries.
- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products.

ANSWER: Abbott denies the allegations of paragraph 167, including all subparts.

168. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

ANSWER: Abbott denies the allegations of paragraph 168.

169. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

ANSWER: Abbott denies the allegations of paragraph 169.

170. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott denies the allegations of paragraph 170.

171. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

ANSWER: Abbott denies the allegations of paragraph 171.

172. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 172.

173. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 173.

174. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 174 and specifically denies that Prevacid® is or was unreasonably dangerous.

175. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

ANSWER: Abbott denies the allegations of paragraph 175 and specifically denies that Prevacid® is or was dangerous.

176. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

ANSWER: Abbott denies the allegations of paragraph 176 and specifically denies that Prevacid® is or was dangerous.

177. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 177 and specifically denies that Prevacid® is or was defective or unsafe.

178. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 178.

179. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 179.

180. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 180.

181. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Abbott denies the allegations of paragraph 181.

182. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 182.

183. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

ANSWER: Abbott denies the allegations of paragraph 183.

184. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff [sic] injuries and damages.

ANSWER: Abbott denies the allegations of paragraph 184.

185. The Defendants failed to provide an adequate warning as to the risks of PPI

Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 185 and specifically denies that Prevacid® is defective in design or formulation, or unsafe.

186. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

ANSWER: Abbott denies the allegations of paragraph 186.

187. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damage.

ANSWER: Abbott denies the allegations of paragraph 187.

188. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Abbott denies the allegations of paragraph 188.

189. The defective nature of the PPI Products was a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 189 and specifically denies that Prevacid® is or was defective.

190. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 190.

191. Defendants' conduct, as described herein, was extreme and outrageous.

ANSWER: Abbott denies the allegations of paragraph 191.

192. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 192.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT III **STRICT PRODUCT LIABILITY – FAILURE TO WARN**

193. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States [*sic*].

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

194. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks.

ANSWER: Abbott denies the allegations of paragraph 194, specifically denies that Prevacid® is or was dangerous or causes kidney or other personal injuries, and further specifically denies that it manufactured Prevacid®.

195. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare

providers of the product, knowing the product could cause serious injury.

ANSWER: Abbott denies the allegations of paragraph 195 and specifically denies that Prevacid® is or was defective.

196. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 196.

197. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 197.

198. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 198.

199. The risks of PPI Products were not open and obvious.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 199.

200. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

ANSWER: Abbott denies the allegations of paragraph 200.

201. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Abbott denies the allegations of paragraph 201 and specifically denies that it is or was a manufacturer of Prevacid®.

202. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, denies that Prevacid® is or was defective or unreasonably dangerous, and further denies the remaining allegations of paragraph 202.

203. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 203, and specifically denies Prevacid® is or was defective or unreasonably dangerous.

204. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 204, and therefore denies them.

205. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

ANSWER: Abbott denies the allegations of paragraph 205, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

206. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 206, and specifically denies that it is or was a manufacturer of Prevacid®.

207. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

ANSWER: Abbott denies the allegations of paragraph 207.

208. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's [sic] healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

ANSWER: Abbott denies the allegations of paragraph 208.

209. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 209.

210. Had Plaintiff and/or Plaintiff's healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

ANSWER: Abbott denies the allegations of paragraph 210.

211. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

ANSWER: Abbott denies the allegations of paragraph 211.

212. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Abbott denies the allegations of paragraph 212.

213. Plaintiff and Plaintiff's healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 213.

214. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

ANSWER: Abbott denies the allegations of paragraph 214.

215. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 215.

216. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 216.

217. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

ANSWER: Abbott denies the allegations of paragraph 217.

218. Defendants' conduct as described herein was a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 218.

219. As a direct and proximate result of Plaintiff [sic] use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such

harm.

ANSWER: Abbott denies the allegations of paragraph 219.

220. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 220.

221. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Further, Defendants' actions and omissions as identified in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 221.

222. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 222.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT IV **NEGLIGENCE**

223. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

224. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 224.

225. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff' [sic] injuries and/or presented an unreasonably high risk of injury.

ANSWER: Abbott denies the allegations of paragraph 225.

226. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI

- Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
- k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
- m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
- n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
- o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
- p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
- q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
- r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
- s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
- t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
- v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;

- w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
- x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
- y. Failing to use due care under the circumstances; and
- z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries and further denies the remaining allegations of paragraph 226, including all subparts.

227. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 227.

228. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

ANSWER: Abbott denies the allegations of paragraph 228.

229. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 229.

230. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

ANSWER: Abbott denies the allegations of paragraph 230.

231. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm (in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ANSWER: Abbott denies the allegations of paragraph 231.

232. Defendants' knowingly and intentionally defectively designed and provided

inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

ANSWER: Abbott denies the allegations of paragraph 232.

233. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff [sic] safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 233.

234. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

ANSWER: Abbott denies the allegations of paragraph 234.

235. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 235.

236. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 236.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT V
NEGLIGENCE PER SE

237. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

238. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

ANSWER: Abbott states that the allegations of paragraph 238 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, Abbott denies them.

239. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

ANSWER: Abbott states that the allegations of paragraph 239 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

240. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

ANSWER: Abbott denies the allegations of paragraph 240.

241. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

ANSWER: Abbott states that the allegations of paragraph 241 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

242. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

ANSWER: Abbott states that the allegations of paragraph 242 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

243. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 243.

244. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 244.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VI

NEGLIGENCE – FAILURE TO TEST

245. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as

if fully set forth herein.

246. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 246 and specifically denies that Prevacid® was unreasonably dangerous.

247. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 247.

248. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 248.

249. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

ANSWER: Abbott denies the allegations of paragraph 249.

250. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 250.

251. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

ANSWER: Abbott denies the allegations of paragraph 251.

252. Adequate testing would have revealed the serious injuries, including but not limited

to renal injury and/or failure and, in some cases, death caused by the use of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 252.

253. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

ANSWER: Abbott denies the allegations of paragraph 253.

254. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

ANSWER: Abbott denies the allegations of paragraph 254.

255. Defendants are strictly liable for Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 255.

256. As a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and/or death; and economic damages incurred through the treatment for the renal failure and renal injuries and/or death caused by PPI Product use.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 256.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VII

BREACH OF EXPRESS WARRANTY

257. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff plead *[sic]* all Counts of this Complaint in the

broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

258. Defendants expressly warranted that their PPI Products were safe and effective to members of the consuming public, including Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 258.

259. Defendants expressly warranted that their PPI Products were safe and effective products for use by members of the consuming public, including the Plaintiff, for the treatment of peptic disorders and did not disclose the material risks that their PPI Products could cause serious kidney injury that may be irreversible, permanently disabling and life-threatening. The representations were not justified by the performance of the PPI Products.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 259.

260. Defendants expressly warranted that their PPI Products were safe and effective to use.

ANSWER: Abbott denies the allegations of paragraph 260.

261. Defendants expressly represented to Plaintiff, Plaintiff's physicians, healthcare providers and/or the FDA that their PPI Products were safe and fit for use for the intended purpose, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, that the side effects they did produce were accurately reflected in the warnings, and that they were adequately tested and fit for their intended use.

ANSWER: Abbott denies the allegations of paragraph 261.

262. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that their PPI Products were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

ANSWER: Abbott denies the allegations of paragraph 262.

263. Plaintiff and/or their healthcare providers reasonably relied on Defendants' express representations.

ANSWER: Abbott denies the allegations of paragraph 263.

264. Defendants' PPI Products do not conform to these express representations because they are not safe and have serious side effects, including kidney injuries and in some cases, death.

ANSWER: Abbott denies the allegations of paragraph 264.

265. Defendants breached their express warranty in one or more of the following ways:
- a. PPI Products, as designed, manufactured, sold and/or supplied by the Defendants, were defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
 - b. Defendants failed to warn and/or place adequate warnings and instructions on their PPI Products;
 - c. Defendants failed to adequately test their PPI Products; and,
 - d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from PPI Products.

ANSWER: Abbott denies the allegations of paragraph 265, including all subparts.

266. Defendants made statements, affirmations and representations of fact concerning their PPI Products through their advertisements, educational campaigns and multi-platform marketing and promotional initiatives directed at consumers, patients and healthcare providers promoting unnecessary and dangerous use and overuse of their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 266.

267. Defendants' statements, affirmations and representations of fact did reach the Plaintiff, and formed a "basis of the bargain" for the Plaintiff's decision to purchase or accept the prescription of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 267.

268. Defendants did not disclose material risk of kidney injuries alleged herein that PPI Products caused.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 268.

269. Defendants' representations concerning the safety and efficacy of their PPI Products were not justified by their performance or benefits.

ANSWER: Abbott denies the allegations of paragraph 269.

270. Defendants expressly warranted that PPI Products were safe and effective for

treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy. In fact, Defendants, through their advertisements, promoted use of PPI Products for ongoing and daily use. Their PPI Products did not conform to Defendants' representations, statements and/or affirmations of fact in terms of the express warranties made to consumers and patients concerning the drugs' safety and efficacy as formulated for use.

ANSWER: Abbott denies the allegations of paragraph 270.

271. Plaintiff reasonably and justifiably relied upon Defendants' representations, statements and/or affirmations of fact that their PPI Products were safe and effective when the Plaintiff chose to purchase, use and continue to use them.

ANSWER: Abbott denies the allegations of paragraph 271.

272. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including Defendants' PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and express warranty of the Defendants in the choosing to use Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 272.

273. Defendants herein breached the aforesaid express warranties as their PPI Products were defective.

ANSWER: Abbott denies the allegations of paragraph 273.

274. Plaintiff's injuries (and in some cases death) were the direct and proximate result of Defendants' breach of their express warranty.

ANSWER: Abbott denies the allegations of paragraph 274.

275. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 275.

276. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 276.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VIII
BREACH OF IMPLIED WARRANTY

277. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff plead [*sic*] all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

278. At the time Defendants marketed, distributed and sold their PPI Products to Plaintiff, Defendants warranted that they were merchantable and fit for the ordinary purposes for which it was intended.

ANSWER: Abbott denies the allegations of paragraph 278.

279. Members of the consuming public, including consumers such as Plaintiff, were intended third party beneficiaries of the warranty.

ANSWER: Abbott denies the allegations of paragraph 279.

280. The PPI Products were not merchantable and fit for their ordinary purpose, because they have a propensity to lead to the serious personal injuries described in this Complaint.

ANSWER: Abbott denies the allegations of paragraph 280.

281. Plaintiff reasonably relied on Defendants' representations that the PPI Products were safe and free of defects and were a safe means of managing and treating symptoms associated with peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 281.

282. At all relevant times hereto, Defendants knew or had reason to know of the purpose for and manner in which users of PPI Products, including Plaintiff, were using the PPI Products, and those users were relying on Defendants' promotional and advertising materials in their selection of the product for that particular use.

ANSWER: Abbott denies the allegations of paragraph 282.

283. Through aggressive healthcare provider promotion and patient advertising, educational, informational and marketing campaigns, Defendants participated in the selection of their PPI Products by healthcare providers, patients and consumers.

ANSWER: Abbott denies the allegations of paragraph 283.

284. At all relevant times hereto, Defendants' PPI Products did not have the requisite clinical safety or efficacy profiles to be deemed fit for the particular purpose of treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 284.

285. Defendants' PPI Products did not conform to this implied warranty of fitness for the use in treating peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 285.

286. Plaintiff was unskilled in the research, design and manufacture of medical drugs and pharmaceutical products, including PPI Products, and reasonably and justifiably relied entirely on the skill, judgment and warranty of the Defendants in the choice to use Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 286.

287. The PPI Products were neither safe nor fit for their intended use nor of merchantable quality, as warranted by Defendants to the Plaintiff, in that PPI Products pose a dangerous risk when used as intended to cause serious kidney injuries.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 287.

288. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiff' [sic] injuries.

ANSWER: Abbott denies the allegations of paragraph 288.

289. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 289.

290. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 290.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT IX
NEGLIGENT MISREPRESENTATION

291. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

292. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug

induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 292.

293. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 293.

294. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 294.

295. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and Plaintiff's healthcare providers, as to the health risks and consequences of the use of their PPI Products.

ANSWER: Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 295.

296. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 296.

297. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demand for, as well as the ultimate prescription, purchase and use of their PPI Products.

ANSWER: Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 297.

298. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 298.

299. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 299.

300. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of PPI Products, and therefore denies them. Abbott denies the remaining allegations of paragraph 300.

301. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 301.

302. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made

conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 302.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT X
FRAUD AND FRAUDULENT MISREPRESENTATION

303. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

304. Defendants fraudulently represented to the medical and healthcare community, patients, consumers and the general public, including the Plaintiff, that their PPI Products had been adequately tested, were safe for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and were accompanied by adequate warnings.

ANSWER: Abbott denies the allegations of paragraph 304.

305. Defendants widely advertised, marketed and promoted their PPI Products as safe and effective medications for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, and widely advertised, marketed and promoted PPIs as a safe for daily and extended use.

ANSWER: Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 305.

306. These representations were made by the Defendants with the intent of deceiving the medical and healthcare community, patients, consumers, the general public and the Plaintiff,

with the intent of inducing the prescription and use of their PPI Products in circumstances that the Defendants knew were dangerous, unsafe and created a high risk of harm.

ANSWER: Abbott denies the allegations of paragraph 306.

307. These representations made by Defendants were false and misleading.

ANSWER: Abbott denies the allegations of paragraph 307.

308. Defendants knew these representations to be false when made and willfully, wantonly and recklessly disregarded whether the representations were true.

ANSWER: Abbott denies the allegations of paragraph 308.

309. Defendants' conduct evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 309.

310. At the time the Defendants made aforesaid representations, Plaintiff used Defendants' PPI Products and was unaware of the falsity of the representations and reasonably believed them to be true.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 310.

311. In reliance on Defendants' misrepresentations, Plaintiff was induced to and did use Defendants' PPI Products, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 311.

312. Defendants knew or should have known that their PPI Products had not been sufficiently tested, were defective in nature and/or lacked adequate and/or sufficient warnings.

ANSWER: Abbott denies the allegations of paragraph 312.

313. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently

dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: Abbott denies the allegations of paragraph 313.

314. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 314.

315. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 315.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XI **GROSS NEGLIGENCE**

316. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States [*sic*].

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

317. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

a. when viewed objectively from Defendants' standpoint at the time of the conduct,

involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or

- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

ANSWER: Abbott denies the allegations of paragraph 317, including all subparts.

318. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

ANSWER: Abbott admits that Plaintiff seeks damages and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of paragraph 318.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XII

FRAUDULENT CONCEALMENT

319. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

320. Prior to Plaintiff's use of Defendants' PPI Products and, during the period in which Plaintiff actually used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of their PPI Products, including information regarding adverse events, pre and post marketing injuries, and epidemiological studies indicating unreasonable risks associated with using PPI Products.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 320.

321. Furthermore, Defendants fraudulently concealed the safety information about the use of their PPI Products. As described herein, Defendants' PPI Products present high risk of kidney injuries not present in other methods and drugs for the treatment of peptic disorders.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 321.

322. These representations and omissions were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase their PPI Products, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

ANSWER: Abbott denies the allegations of paragraph 322.

323. At the time the aforesaid representations and omissions were made by the Defendants, and at the time the Plaintiff used Defendants' PPI Products, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® and therefore denies them. Abbott denies the remaining allegations of paragraph 323.

324. Defendants fraudulently concealed the safety issues associated with PPI use to induce Plaintiff to purchase and use, and physicians to prescribe and/or recommend their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 324.

325. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on Defendants'

omissions and representations in using or prescribing the PPI Products, thereby causing Plaintiff to sustain severe and permanent personal injuries. Defendants knew, were aware or should have been aware that their PPI Products had not been sufficiently tested, were defective in nature and/or that their PPI Products lacked adequate and/or sufficient warnings.

ANSWER: Abbott denies the allegations of paragraph 325.

326. Defendants knew or should have known that their PPI Products had a potential to cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate and/or down-played warnings.

ANSWER: Abbott denies the allegations of paragraph 326.

327. Defendants had a duty to provide consumers, patients and healthcare providers with full, complete, accurate and truthful information concerning their PPI Products, including the appropriate use of the product.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 327.

328. Defendants also had a duty to disclose material information about serious side effects to consumers such as the Plaintiff.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 328.

329. By virtue of Defendants' omissions and partial disclosures about the medications, in which Defendants touted their PPI Products as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks described in this Complaint.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty

under the law at all times. Abbott denies the remaining allegations of paragraph 329.

330. Plaintiff and/or Plaintiff's healthcare providers reasonably relied on these material misrepresentations and omissions when deciding to prescribe, recommend, purchase and/or consume Defendants' PPIs Products.

ANSWER: Abbott denies the allegations of paragraph 330.

331. Plaintiff's healthcare providers were not provided the necessary information by the Defendants to provide an adequate warning to the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 331.

332. Plaintiff was not provided the necessary information by Defendants to provide an adequate warning to the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 332.

333. The PPI Products were improperly marketed to the Plaintiff and/or Plaintiff's healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about the risks associated with PPI use.

ANSWER: Abbott denies the allegations of paragraph 333.

334. Plaintiff would not know, in the exercise of reasonable diligence, that Defendants' statements concerning their PPI Products were knowingly and intentionally false and misleading, or that Defendants had not disclosed material facts and information to the Plaintiff and/or the Plaintiff's healthcare providers that would have been material to the choice of treatment.

ANSWER: Abbott denies the allegations of paragraph 334.

335. As a direct and proximate result of Defendants' malicious and intentional concealment of material information from Plaintiff and Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff' *[sic]* injuries (and in some cases death).

ANSWER: Abbott denies the allegations of paragraph 335.

336. Prior to the Plaintiff's use of Defendants' PPI Products and during the period in which Plaintiff used Defendants' PPI Products, Defendants fraudulently suppressed material information regarding the safety and efficacy of the drugs, including information regarding increased risk of kidney injuries.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore

denies them. Abbott denies the remaining allegations of paragraph 336.

337. Had Plaintiff been aware of the hazards associated with the PPI Products, Plaintiff would have used a safer alternative treatment for peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy, would not have consumed the PPI Products and/or would have reduced the duration or quantity of use.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 337.

338. Defendants' conduct was reckless, willful, wanton, and outrageous, and manifested a reckless indifference for the safety and well-being of patients and consumers, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 338.

339. As a direct and proximate result of Defendants' intentional and willful fraudulent concealment of material facts and information from the Plaintiff and Plaintiff's healthcare providers, Defendants caused, and increased the risk of harm of, the injuries and damages suffered by the Plaintiff from the use of Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 339.

340. Had Plaintiff been aware of the hazards associated with PPI use as concealed by Defendants, Plaintiff would have not have accepted PPI treatment and would have accepted a safer and more effective alternative.

ANSWER: Abbott denies the allegations of paragraph 340.

341. Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with their PPI Products for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

ANSWER: Abbott denies the allegations of paragraph 341.

342. Defendants conduct is outrageous and shocks the conscience, and knowingly and intentionally placed considerations of financial gain, revenues and profits, market share and marketing advantage over patient safety and well-being.

ANSWER: Abbott denies the allegations of paragraph 342.

343. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries

(in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care. Defendants' conduct, as described herein, was extreme and outrageous.

ANSWER: Abbott denies the allegations of paragraph 343.

344. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 344.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT XIII
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

345. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

346. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 346.

347. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, 815 ILCS 505/1.

ANSWER: Abbott states that the allegations of paragraph 347 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies them.

348. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 348.

349. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

ANSWER: Abbott denies the allegations of paragraph 349.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;

- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
- d. Prejudgment interest;
- e. Post-judgment interest;
- f. Awarding reasonable attorneys' fees;
- g. Awarding the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of Plaintiff's Prayer for Relief.

AFFIRMATIVE AND OTHER DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Abbott in this matter. Abbott therefore asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if facts warrant, Abbott may withdraw any of these defenses as may be appropriate. Further, Abbott reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Abbott states as follows:

1. Plaintiff's Complaint against Abbott fails to state a claim upon which relief may be granted.
2. This Court lacks personal jurisdiction over Abbott with respect to Plaintiff's claims, and thus the Complaint should be dismissed.
3. Each and every claim alleged or raised in the Complaint is barred by the applicable statute of limitations, the applicable statute of repose, the doctrine of prescription, and/or is otherwise untimely.

4. Each and every claim alleged or raised in the Complaint is barred by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and Abbott's only obligation, if any, would be to warn the prescribing health care provider, which obligation was fulfilled.

5. Abbott gives notice that, to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Abbott intends to rely upon same in defense of this action.

6. Each and every claim alleged or raised in the Complaint is barred by the doctrines of laches, estoppel, waiver, and/or statutory and regulatory compliance.

7. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening and/or supervening cause or causes, and any act or omission on the part of Abbott was not the proximate and/or competent producing cause of such alleged injuries and damages.

8. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses may have been caused, may have been solely caused, may be barred, and/or may be limited in whole or in part by the contributory negligence or comparative fault and/or comparative negligence of Plaintiff.

9. In the alternative, without waiving its denial of liability to Plaintiff, Abbott states that, assuming that 100% represents the total combined fault of the parties to this action, the fault on the part of Plaintiff was more than 50% of the total proximate cause of the alleged injuries and, therefore, there is no liability on the part of Abbott. In the alternative, in the event that it is found that fault on the part of Plaintiff is less than 50% of the proximate cause of the alleged injury, then

the amount of the verdict awarded to Plaintiff must be reduced in accordance with the percentage of that fault.

10. If Plaintiff has sustained injuries or losses, as alleged in the Complaint, Plaintiff's claims regarding such injuries or losses may be barred or reduced by Plaintiff's knowingly, voluntarily, and/or willfully assuming the risk of any injury as the result of the consumption of, administration of, or exposure to the product at issue or any medicine or pharmaceutical preparation manufactured or distributed by another manufacturer.

11. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Abbott and over whom Abbott had no control and for whom Abbott may not be held accountable.

12. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by circumstances, events, or persons over whom Abbott had no authority or control and for which Abbott is not answerable in damages to Plaintiff.

13. To the extent Plaintiff's claims were caused by the actions, omissions, or products of persons or entities over whom Abbott has no dominion, authority, or control, Abbott is entitled to have its liability to the Plaintiff, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

14. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse or abuse of the product at issue after it left the control of Abbott.

15. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were the result of unavoidable circumstances that could not have been prevented by any person, including Abbott.

16. Abbott denies any liability, but if Abbott is ultimately found liable to Plaintiff, then Abbott shall only be liable for its equitable share of Plaintiff's recovery since any such liability would be insufficient to impose joint liability.

17. If Plaintiff recovers from Abbott, Abbott is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence of fault proximately caused or contributed to cause Plaintiff's alleged damages.

18. Any verdict of judgment rendered against Abbott must be reduced by the comparative fault of other persons or entities.

19. Any verdict of judgment rendered against Abbott must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part for any past or future loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

20. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by the off-label use of the product at issue that Abbott did not proscribe and for which Abbott is not legally responsible.

21. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated physical, physiological, medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions, or natural courses of conditions for which Abbott is not legally responsible.

22. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

23. Plaintiff did not detrimentally rely on any labeling, warnings, or information concerning Prevacid®.

24. Any warranties made by Abbott to Plaintiff were disclaimed.

25. To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are barred for lack of timely notice of any breach or alleged failure.

26. Abbott did not sell or distribute Prevacid® directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims are therefore barred by lack of privity.

27. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

28. Any claim for breach of express warranty must fail because Plaintiff failed to allege any representations about the product at issue giving rise to an express warranty.

29. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Abbott in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of Prevacid®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

30. Plaintiff cannot establish that any reasonable alternative design would have rendered the product at issue safer overall, and that the failure to adopt a reasonable alternative design rendered

the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

31. Plaintiff cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risks of harm posed by the product at issue would have rendered the product safer overall, and that the failure to provide such alternative instructions or warnings rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

32. Each and every claim alleged or raised in the Complaint is barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

33. Each and every claim alleged or raised in the Complaint is barred in whole or in part because legally adequate "directions or warnings" were provided as to the use of the product at issue and any other medicine or pharmaceutical preparation to which Plaintiff attribute Plaintiff's alleged damages within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

34. Each and every claim alleged or raised in the Complaint is barred by Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

35. Each and every claim alleged or raised in the Complaint is barred by comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

36. Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of the product at issue.

37. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government, and/or the *Noerr-Pennington* doctrine.

38. Each and every claim alleged or raised in the Complaint is barred in whole or in part by Plaintiff's failure to mitigate alleged damages.

39. Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate their claims to negligence.

40. All activities of Abbott as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to any alleged misrepresentations or omissions are barred.

41. Each and every claim alleged or raised in the Complaint is barred because, if the product at issue was unsafe, which Abbott denies, then it was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk, given the scientific knowledge available when the product was marketed.

42. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical product at issue provide net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

43. Plaintiff, or Plaintiff's physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of Prevacid® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings.

44. Plaintiff's claims are barred because Prevacid® was consistent with and exceeded consumer expectations.

45. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

46. Abbott had a good faith belief in the lawfulness of its actions.

47. The advertisements and labeling with respect to the product at issue were not false or misleading and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution and the state Constitution.

48. The public interest in the benefit and availability of the product at issue precludes liability for risks, if any, resulting from any activities undertaken by Abbott, that were unavoidable, given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product at issue, then such risk, if any, is outweighed by the benefit of the product.

49. Plaintiff's failure to warn claim is barred given that Abbott had no duty to warn of risks of which Abbott neither knew nor should have known at the time Prevacid® was designed, distributed, and manufactured.

50. At all relevant times, Prevacid® was manufactured and distributed in a reasonable and prudent manner, based upon available medical and scientific knowledge, and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

51. To the extent there were any risks associated with the use of Prevacid® that Abbott knew or should have known and that gave rise to a duty to warn, which Abbott denies, Abbott at all

times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

52. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

53. Each and every claim alleged or raised in the Complaint may be barred because Plaintiff has failed to comply with the conditions precedent or subsequent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

54. Each and every claim alleged or raised in the Complaint may be barred in whole or in part by the doctrine of informed consent.

55. Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources.

56. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

57. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Abbott, if any, should be reduced accordingly.

58. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or release of claims.

59. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

60. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, or suppression.

61. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Abbott and all of its activities with respect to the product at issue have been and are conducted under the supervision of the FDA.

62. Each and every claim alleged or raised in the Complaint and based on allegedly inadequate warnings is barred even if Abbott failed to provide adequate warnings with respect to known or potential dangers or risks associated with the use of the product, because physicians prescribing the product at issue either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or that should be known to members of the profession.

63. Any injuries or damages Plaintiff and Decedent may have sustained may have been caused by a substantial change in the product at issue after leaving the possession, custody, and control of Abbott, if applicable.

64. The common law claims and theories of liability set forth in the Complaint are barred by the doctrine of federal preemption. Abbott's conduct conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, each and every claim alleged or raised in the Complaint is barred in whole or in part under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

65. The New Drug Application for Prevacid® was approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such

statutes and regulations by Abbott, as applicable, demonstrates that Prevacid® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiff's claims against Abbott. Compliance with any applicable statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of Prevacid®, and that it was neither defective nor unreasonably dangerous.

66. Plaintiff's claims are barred because Prevacid® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiff's recovery.

67. The warnings and instructions accompanying Prevacid® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

68. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding Prevacid® and other drugs in its class.

69. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

70. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

71. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid in the United States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

72. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

73. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

74. All labeling for Prevacid® has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder. Plaintiff's claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent Plaintiff asserts that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ____ (2019). Plaintiff's claims also are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives. Additionally, Plaintiff's design defect claims are barred by the doctrine of federal preemption under *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

75. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

76. Plaintiff's attempt to collect damages from Abbott based on Plaintiff's and Decedent's alleged injuries caused by a product that Abbott may not have manufactured or sold violates Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States

Constitution; and similar or corresponding provisions of the applicable states' Constitutions, the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the applicable states' Constitutions.

77. Plaintiff did not suffer any actual injury, loss, or damages because of Plaintiff's alleged use of Prevacid®.

78. Plaintiff's claims may be barred, in whole or in part, because Abbott did not design, manufacture, promote, or sell the products which form the basis of Plaintiff's claims.

79. All or part of the injuries, damages, and/or losses, if any, sustained by Plaintiff or Decedent, if proven, were caused in whole or in part by the acts or omissions of others for whose conduct Abbott is not responsible and/or resulted from conditions or events unrelated to any conduct by Abbott.

80. Some or all of Plaintiff's claims and/or damages, if any, may be barred, limited, or offset by the law of other states that may govern under this jurisdiction's choice of law provisions and resulting application of law from other jurisdictions. These may include, without limitation, another state's product liability statute, its applicable statute of limitations, its modified comparative fault doctrine, and limitations on the award of noneconomic and punitive damages.

81. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

82. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages ("punitive damages") for the conduct that allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Abbott's rights as reserved by the Fifth, Seventh, Eighth, and

Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution(s).

83. Any claim by Plaintiff for punitive damages is in contravention of Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; similar provisions in the states of Plaintiff's citizenship; and/or the common law and public policies of such states.

84. To the extent that Plaintiff seeks punitive damages, said claim is unconstitutionally vague and/or overly broad because of the lack of clear standards. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitutions, and applicable state common law and public policies.

85. Plaintiff's claim for punitive damages against Abbott cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the

basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Abbott; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards. Any such verdict would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under applicable state common law and public policies.

86. Unless Abbott's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

87. To the extent that Plaintiff seeks punitive damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and subsequent cases, including *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

88. To the extent that Plaintiff seeks punitive damages, any award against Abbott on any grounds other than its conduct with regard to the product Plaintiff used would be improper under applicable constitutional principles.

89. No act or omission of Abbott was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiff or with conscious disregard and indifference to the rights, safety and welfare of Plaintiff and, therefore, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

90. To the extent that Plaintiff seeks punitive damages, such claim is barred because the product at issue, and its labeling, was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

91. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Abbott and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the applicable state constitutions.

92. With respect to Plaintiff's demand for punitive or exemplary damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and the applicable state law.

93. Plaintiff's Complaint seeks damages in excess of those permitted by law. Abbott asserts any statutory or judicial protection from punitive or exemplary damages which is available under

the applicable law, including applicable statutory or other caps or limitations on the recovery or punitive or exemplary damages, and any award of punitive or exemplary damages is barred.

94. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, because Plaintiff may lack capacity or standing to bring the claims alleged.

95. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Abbott to determine all of its legal, contractual, and equitable rights, Abbott reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent defenses ascertained through further investigation and discovery.

96. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

97. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid® in the United States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

98. Discovery or investigation may reveal that some or all of the claims alleged by Plaintiff are barred by the doctrines of accord and satisfaction.

99. Abbott is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

100. Plaintiff's recovery as against Abbott should be barred in accordance with Ill. Comp. Stat. Ann. ch. 735, 5/2-621.

101. Plaintiff fails to state a claim for unlawful conduct under Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable "Deceptive

Trade Practices Act,” because Abbott completely complied with the applicable law in connection with the distribution of Prevacid®.

102. Plaintiff fails to state a claim for false or misleading business practices under Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable “Deceptive Trade Practices Act,” because Abbott’s sale of Prevacid® was not false or misleading.

103. Plaintiff’s claims are barred in whole or in part because Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable “Deceptive Trade Practices Act,” is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the Illinois Constitution.

104. Plaintiff’s claims are barred in whole or in part because Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable “Deceptive Trade Practices Act,” unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

105. Plaintiff fails to properly plead any claims under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, with sufficient particularity.

106. Plaintiff fails to state a cognizable claim under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, because the majority of the alleged violations of the Illinois Consumer Fraud and Deceptive Business Practices Act occurred outside of Illinois.

107. Plaintiff’s claims asserted under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, are barred because Plaintiff does not allege proximate causation for Plaintiff’s claimed injuries as required under Illinois law.

108. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code, Ill. Comp. Stat. Ann. ch. 810, 5/2-314, and/or other applicable law.

109. Abbott adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

110. Abbott is entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of applicable state and federal law.

JURY DEMAND

Abbott hereby demands a trial by jury by the maximum number of jurors permitted by law on all issues so triable.

PRAYER

WHEREFORE, having answered, Abbott requests that this Court enter judgment in its favor and against Plaintiff on all counts and allegations of the Complaint and that the Court award Abbott its costs and such other relief as it deems just and proper.

Dated: July 29, 2019

Respectfully submitted,

By: /s/ Jennifer A. Foster

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CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served on July 29, 2019 via electronic mail on the following:

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/s/ Jennifer A. Foster
Jennifer A. Foster

Return Date: No return date scheduled
Hearing Date: No hearing scheduled
Courtroom Number: No hearing scheduled
Location: No hearing scheduled

Cook County Atty No. 64078

FILED

11/15/2019 12:05 AM

DOROTHY BROWN

CIRCUIT CLERK

COOK COUNTY, IL

2019L005876

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS**COUNTY DEPARTMENT, LAW DIVISION**

RONALD SUMMERS

7376107

Plaintiff,**vs.****CASE NO:** 2019L005876

TAKEDA PHARMACEUTICALS U.S.A.,
INC.; TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA
PHARMACEUTICAL COMPANY
LIMITED; TAKEDA DEVELOPMENT
CENTER AMERICAS, INC., f/k/a TAKEDA
GLOBAL RESEARCH & DEVELOPMENT
CENTER, INC.; TAP PHARMACEUTICAL
PRODUCTS, INC. f/k/a TAP HOLDINGS,
INC.; NOVARTIS CORPORATION,
NOVARTIS PHARMACEUTICALS
CORPORATION; NOVARTIS VACCINES
AND DIAGNOSTICS, INC.; NOVARTIS
INSTITUTES FOR BIOMEDICAL
RESEARCH, INC; NOVARTIS
CONSUMER HEALTH INC. d/b/a GSK;
GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC

Defendants.

**This Motion Relates To The Cases
Consolidated on July 29, 2019**

PLAINTIFFS' MOTION FOR LEAVE TO FILE AMENDED COMPLAINTS

NOW COME the Plaintiffs, by and through the undersigned counsel, and respectfully move this Court, pursuant to Section 2-616 of the Illinois Code of Civil Procedure, for an entry of an order allowing Plaintiffs leave to file Amended Complaints. In support thereof, Plaintiffs state as follows:

1. On July 29, 2019, Judge Flannery issued an order consolidating sixty-eight (68) cases into the above named "lead" case.

2. Certain defendants have filed Motions to Dismiss in sixty (60) of the consolidated cases. A list of the cases subject to Motions to Dismiss is attached hereto.
3. Plaintiffs seek to amend the complaints subject to Motions to Dismiss to address certain issues raised by defendants.
4. Plaintiffs' proposed Amended Complaints at Law are attached hereto as Exhibits 1 through 60.
5. Permitting the filing of the amended complaints would be just and reasonable because no final judgment has been rendered and it more properly states the causes of action each plaintiff has against the defendants.

WHEREFORE, Plaintiffs respectfully request that this Court enter the proposed Order Granting Plaintiff's Motion for Leave to File Amended Complaints and to order the amended complaints at law attached hereto as Exhibits 1 through 60 deemed as filed in each corresponding consolidated case.

Dated: November 14, 2019

Respectfully submitted,



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ATTORNEYS FOR PLAINTIFF

LIST OF CONSOLIDATED CASES WITH PENDING MOTIONS TO DISMISS

Baily-Freely, Kimberly	2019L006058
Ballard, Pearline	2019L006069
Barden, William	2019L005952
Benoit, Harold	2019L006071
Boehm, Beverly	2019L006016
Bond, Tawana	2019L005958
Burgdorf, Randi	2019L006021
Bush-Sanders, Nicole	2019L006049
Carroll, Dennis	2019L005962
Chasse, Tammy	2019L005971
Cielocha, Sharon	2019L005982
Climons, James	2019L005988
Cooper, Michelle	2019L005994
Davis, George	2019L006000
Devriendt, Richard	2019L006004
Dewese, Harold	2019L006006
Dye, Chavetta	2019L006042
Ebler, Sr., John	2019L006008
Evans, Sammie	2019L006010
Freeman, Dorothy	2019L005987
Funches, Dawn	2019L005904
Gammon Kossman, Sharon	2019L006059
Gipson, Gale	2019L006011
Green, Allen	2019L006017
Gregory, Elizabeth	2019L006035
Harmon, Rhonda	2019L006047
Irons, James	2019L006024
Isley, Jackie	2019L006032
Iverson, Jacqueline	2019L006038
Jackson, Debbie	2019L005995

Johnson-Poellinetz, Queen	2019L006014
Jones, Loretta	2019L006040
Jones, Melanthia	2019L006043
Klein, Wanda	2019L006023
Lind, Carolyn	2019L006030
Lovall, Robert	2019L006031
Medious-Sanders, Jacqueline	2019L006045
Miller, Barry	2019L005985
Moore, Kathy	2019L005978
O'Connor, Edward	2019L006062
Pacheco, Faustino P	2019L005975
Pennington, James	2019L005983
Pierson, Karolin	2019L005991
Powers, Pamela	2019L005993
Ragner, Ronald	2019L006001
Reece, Robert	2019L006061
Schumaker, Lawrence	2019L006041
Sladek, James	2019L006060
Smith, Alverner	2019L006067
Smith, Kelvin	2019L006033
Stewart, Antoinette	2019L006025
Swanigan, Rebecca	2019L005973
Swope, Alfreda	2019L005974
Taylor, Yolanda	2019L005984
Topel, Daniel	2019L005979
Wade, Holly	2019L005999
Young, Sheila	2019L006013
Bramlet, Mark Allen	2019L005954
Miller, Beverly A.	2019L005878
Tracy, William	2019L005946

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of November, I electronically filed the forgoing document with the Clerk of the Court using the File & Serve Xpress system which will send notification of such filing to the File & Serve Xpress participants registered to receive service in this member case.

/s/Brian J. Perkins

Brian J. Perkins

EXHIBIT 37

COUNTY DEPARTMENT, LAW DIVISION

This Document Relates To:

JACQUELINE MEDIOUS - SANDERS

Plaintiff,

vs.

ABBOTT LABORATORIES; TAKEDA
PHARMACEUTICALS USA,
INC.; TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA
DEVELOPMENT CENTER AMERICAS,
INC. F/K/A TAKEDA GLOBAL
RESEARCH & DEVELOPMENT CENTER,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED

Defendants.

CASE NO: 2019L006045

**AMENDED COMPLAINT WITH
JURY
DEMAND ENDORSED HEREON**

.....

COMES NOW, Plaintiff(s), Jacqueline Medious-Sanders, by and through the undersigned counsel, and brings this Amended Complaint against Abbott Laboratories; Takeda Pharmaceuticals USA, Inc. (“TPUSA”); Takeda Pharmaceuticals America, Inc. (“TPA”); Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. (“TDC Americas”); Takeda Pharmaceutical Company Limited (“TPC”), hereinafter collectively referred to as “Defendants” and for their Complaint and Jury Demand allege as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts to date, regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

3. As more particularly set forth herein, the Plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Prevacid.

4. PPIs are a product approved by Food and Drug Administration ("FDA") with approved indications for reduction of gastric acid production in order to treat such conditions as duodenal ulcer and its recurrence, NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions, including Zollinger-Ellison Syndrome.

5. As a result of the defective nature of PPIs hereafter alleged, persons who ingested this product, including the Plaintiff, have suffered and may continue to suffer from certain kidney injuries, including chronic kidney disease ("CKD").

6. Defendants, individually and collectively, as heretofore alleged, failed to conduct proper testing of their PPI products, design studies aimed at detecting renal dysfunction for which Defendants knew or should have known could occur with their PPI products, failed to properly warn physicians prescribing PPIs to monitor their patients for adverse renal events and to promptly discontinue said PPIs if signs of kidney dysfunction occurred, failed to properly monitor renal adverse events related to their PPIs in the post-marketing period and failed to bring to the attention of regulators, prescribing physicians and the consuming public a myriad of concerning reports received by the Defendants and reported in the peer-reviewed scientific literature.

7. It is further alleged that Defendants, individually and collectively, purposely concealed (and continue to conceal to this day) their knowledge of PPIs' unreasonably dangerous effects on the kidneys from Plaintiff, prescribing physicians, including Plaintiff's prescribing physician, other consumers, and the medical community at large. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the elevated risk of kidney injuries related to ingestion of PPIs, in particular ingestion for longer periods of time beyond those indicated periods of usage and/or in vulnerable populations such as the elderly and/or those persons who are at risk for kidney disease as a result of underlying illnesses and comorbidities.

8. In failing to warn prescribing physicians and the consuming public, including the Plaintiff, of the aforesaid dangers associated with their PPI products, prescribers and their patients were prevented from knowing that continued and prolonged use of PPIs could cause and/or contribute to severe and irreversible kidney injury and/or exacerbate underlying kidney disease in patients sustaining such kidney injury.

9. It is further alleged that the Defendants, individually and collectively, failed to contraindicate PPIs for use by individuals who were already at an increased risk of kidney injury, and failed to contraindicate PPIs for concomitant use with other known nephrotoxic

medications, such as NSAIDs, thereby compounding the potential for persons, such as the plaintiff, to suffer additional and repeated kidney insults followed by chronic and irreversible kidney injuries.

10. It is further alleged that the Defendants, individually and collectively, encouraged and promoted the use of PPIs beyond the indications approved by FDA, including the use of PPIs beyond the prescribed periods approved in the label, including pervasive advertising campaigns aimed at prescribers and the consuming public concerning the “little purple pill” for use with “frequent heart burn” and actively encouraging “daily use” of said PPIs when defendants knew that these products were not so indicated.

11. As a result of Defendants’ individual and collective actions, inactions, omissions, and purposeful conduct, as hereafter alleged, Plaintiff was injured due to his ingestion of PPIs, and caused to suffer severe and permanent injuries as herein alleged and will continue to suffer chronic and irreversible injuries and damages as herein alleged. Plaintiff accordingly seeks damages associated with said injuries and damages.

PARTIES, JURISDICTION & VENUE

13. This Complaint is filed on behalf of the Plaintiff and/or Decedent’s listed here in, and if applicable, Plaintiff’s and/or Decedent’s spouses, children, decedents, Estates, Wards, beneficiaries and heirs.

14. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this court has in personam jurisdiction over the Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

15. This Court has personal jurisdiction over Defendants, pursuant to, and consistent with, Illinois’ long-arm statute (735 ILCS 5/2-209) and the Constitutional requirements of Due

the following:

- a. Defendants transacted business in the State of Illinois, 735 ILCS 5/2-209(a)(1);
- b. Defendants made or performed a contract or promise substantially connected within this state, 735 ILCS 5/2-209(a)(7);
- c. Defendants do business in and within Illinois, 735 ILCS 5/2-209(b)(4); and;
- d. Requiring Defendants to litigate this claim in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

16. Defendants marked, promoted, and sold PPI Products in this State and in Cook County in particular. Additionally, Defendant Abbot Laboratories has its place of business in Abbott Park, Illinois along with the following Takeda entities that maintain their place of business in Deerfield, Illinois: Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited (“TPC”). These entities developed, researched, tested, and designed their respective PPI Products within or immediately surrounding Cook County. These ties represent a lasting, significant connection to this venue. Accordingly, venue is appropriate before this Court.

17. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court.

I. PLAINTIFF

18. Plaintiff, Jacqueline Medious-Sanders, resides in Cook County, Illinois and resided in Cook County, Illinois at all times relevant.

a. Plaintiff, Jacqueline Medious-Sanders, ingested the following PPI products

sold by the Defendants from at least approximately January 2003 to June 2008:

Prevacid.

- b. As a direct and proximate result of Plaintiff's use of the PPI(s), Prevacid, Plaintiff has suffered and was treated for Chronic Kidney Disease ("CKD"), in approximately January 2010 with related sequelae.

19. Plaintiff alleges, as set forth more fully below, that she developed CKD as a direct and proximate cause of her ingestion of Defendants' defective PPI product, Prevacid, and that she was prevented from obtaining her best chance of cure based upon ongoing and repeated exposures to Defendants' PPI product.

II. DEFENDANTS

19. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, IL. 60064.

20. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

21. Defendant Abbott manufactures and markets Prevacid in the United States.

22. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

23. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

24. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived

States related to Prevacid.

25. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

26. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

27. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

28. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

29. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

30. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

31. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

32. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

33. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent, authorization and approval.

34. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Dexilant (dexlansoprazole), Prevacid, Prevacid 24HR and Protonix products.

35. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid and Prevacid 24HR products.

36. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

37. The Takeda Defendants manufacture and market each of these prescription Prevacid formulations in the United States.

38. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

39. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

40. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

41. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived

States related to PPI Products.

42. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

43. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

FACTUAL ALLEGATIONS

A. General Background: Proton Pump Inhibitors

44. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

45. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

46. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

47. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

48. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

49. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

B. PPI Products Cause Severe Kidney Injuries

50. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

51. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

i. PPI-Induced Acute Interstitial Nephritis (“AIN”)

52. Since 1992, numerous case reports have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

53. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology’s Kidney International finding that PPI Product use, by way of AIN, left most patients “with some level of chronic kidney disease.”

54. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, “Systematic review: proton pump inhibitor-associated acute interstitial nephritis.” The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

55. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data

from the World Health Organization Collaborating Centre for International Drug Monitoring, “where PPI-induced AIN is disproportionately present in the database.” Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

56. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen’s Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

57. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

58. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

59. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

60. In December of 2014, all labels for prescription PPI Products were required to include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

61. To this date, Defendants’ over-the-counter PPI Products do not include a warning or any risk information about AIN.

62. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left

untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

63. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

64. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

65. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

66. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

67. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

68. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

69. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ii. PPI-Induced Acute Kidney Injury (“AKI”)

70. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

71. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

72. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

73. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

74. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

iii. PPI-Induced Chronic Kidney Disease (“CKD”)

75. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

76. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

77. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

78. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

79. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis

of kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

80. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

81. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int’l 1482 (2017).

82. To date, the labeling for Defendants’ PPI Products lack adequate risk information about CKD.

C. PPI Products Cause Rebound Acid Hypersensitivity, Worsening GERD and Acid Reflux, Creating Dependency

83. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

84. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as “rebound acid hypersecretion” and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

85. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

86. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases beyond their pre-PPI treatment levels.

87. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

88. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

89. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

90. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

91. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

D. Safer Alternatives to PPIs

92. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

- a. The use of over-the-counter calcium carbonate tablets that have been available since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H2-receptor antagonists (also known as “H2 Blockers”) that were developed in the late 1960s. H2 Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H2 Blockers include Zantac, Pepcid and Tagamet. H2 Blockers are not associated with an increased risk of kidney injuries.

93. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

94. Consumers, including Plaintiff, who have used Defendants’ PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

E. Injuries Resulting from PPI Products

95. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants’ (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

96. As a result of the defective nature of Defendants’ PPI Products, persons who ingested Defendants’ PPI Products have been exposed to significant risks stemming from

unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

97. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

98. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

F. Defendants' Actively Concealed the Dangers Associated with Use of PPI Products

194. From as early as the 1980s up through and including the present day, there have been post-marketing safety reports received by each of these defendants directly and in the form of published scientific and medical peer-reviewed literature case reports, case series, observational studies and meta-analyses that demonstrate that PPIs *as a class* cause kidney injuries, including, *inter alia*, AIN, AKI, CKD, ESRD and/or renal failure (acute and chronic).

195. AIN is a sub-type of AKI that manifests specifically as inflammation in the interstitium and tubules, structures that are contained within the nephron, also known as the "functional unit" of the kidney. If left unchecked or if treated insufficiently, AIN can progress to a chronic state, i.e., Chronic Interstitial Nephritis, that in turn can progress to downstream effects of CKD and ESRD, especially if the offending agent, i.e., PPI products, are not withdrawn.

196. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center, led by Stephen Ruffenach, published the first article associating PPI usage with kidney injuries in *The American Journal of Medicine*, followed by years of reports from national adverse drug registries describing this association.

In 1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.¹

197. Between 1995 and 1999, Nicholas Torpey, et al. conducted a single-center retrospective analysis of renal biopsy results from 296 consecutive patients to determine the etiology of acute tubule-interstitial nephritis (TIN).² Acute AIN was identified in 24 (8.1%) biopsies. Eight out of fourteen cases with presumed drug-related AIN could be attributed to the PPIs omeprazole and lansoprazole.

198. Defendants, individually and collectively, responsible for post-marketing surveillance, knew or should have known that between 1992 and 2004 more than 23 cases of biopsy-proven AIN secondary to omeprazole (Prilosec) had been reported.

199. In 2004, Defendants, individually and collectively, knew or should have known of 8 biopsy-proven cases reported from Norwich University Hospital in the United Kingdom.³

200. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI were causal. “Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure.”⁴

¹ Badov, D., et al. Acute Interstitial Nephritis Secondary To Omeprazole, *Nephrol Dial Transplant* (1997) 12: 2414–2416.

² Torpey, N., et al. *Drug-Induced Tubulo-Interstitial Nephritis Secondary To Proton Pump Inhibitors: Experience From A Single UK Renal Unit*, *Nephrol. Dial. Transplant.* (2004) 19: 1441–1446.

³ *Id.*

⁴ Simpson, I., et al., *PPI and Acute Interstitial Nephritis*, *NEPHROLOGY* (2006)11: 381-85.

201. Furthermore, in the New Zealand study, Defendants, individually and collectively, knew or should have known that twelve of the reported cases were biopsy-proven cases of renal failure caused by tubulointerstitial injury.

202. In 2006, Nimeshan Geevasinga, et al., found “evidence to incriminate all the commercially available PPIs, suggesting there is a class effect” with regard to PPI-induced AIN.⁵ “Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease.” This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases at two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified eighteen cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional thirty-one cases of “biopsy proven interstitial nephritis.” An additional ten cases of “suspected interstitial nephritis,” twenty cases of “unclassified acute renal failure,” and twenty-six cases of “renal impairment” were also identified. “All Five commercially available PPIs were implicated in these cases.”

203. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.⁶

204. In 2006, researchers at the Yale School of Medicine conducted a case series published in the *International Society of Nephrology’s Kidney International* finding that PPI use, by way of AIN, left most patients “with some level of chronic kidney disease.”

205. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks

⁵ Geevasinga, N., et al. *Proton Pump Inhibitors and Acute Interstitial Nephritis*, CLINICAL GASTROENTEROLOGY AND HEPATOLOGY, (2006)4:597-604.

⁶ Ian J. Simpson, Mark R. Marshall, Helen Pilmore, Paul Manley, Laurie Williams, Hla Thein, David Voss, *Proton pump inhibitors and acute interstitial nephritis: Report and analysis of 15 cases*, (September 29, 2006).

associated with PPIs including AIN, because, as alleged in the petition, there was no detailed risk information on any PPI for this adverse effect.”

206. In 2013, Klepser, et al. found that “patients with a renal disease diagnosis were twice as likely to have used a previous prescription for a PPI.”⁷ Klepser’s study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

207. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy.⁸ Researchers further noted that “a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease.”

208. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data in New Zealand to estimate the relative and absolute risks of acute interstitial nephritis resulting in hospitalization or death in users of PPIs.⁹ The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of acute interstitial nephritis for patients currently taking PPIs.

209. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

210. The FDA noted “that the prescription PPI labeling should be consistent with regard to this risk” and that “there is reasonable evidence of a causal association.”

211. In December of 2014, the labels of prescription PPIs were updated to read:

Acute interstitial nephritis has been observed in

⁷ Klepser, D., et al. Proton Pump Inhibitors and Acute Kidney Injury: A Nested Case-Control Study, BMC NEPHROLOGY (2013) 14:150.

⁸ Sampathkumar, K., et al. *Acute Interstitial Nephritis Due to Proton Pump Inhibitors*, INDIAN J. NEPHROLOGY (2013) 23(4): 304-07.

⁹ Blank, M., et al. *A Nationwide Nested Case-Control Study Indicates an Increased Risk of Acute Interstitial Nephritis with Proton Pump Inhibitor Use*, KIDNEY INTERNATIONAL (2014) 86, 837–844.

patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

212. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.¹⁰ The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n = 10,482) and the Geisinger Health System (n = 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14–1.96).

213. “Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted hazard ratio 1.64, 95% confidence interval 1.22–2.21). The results were then validated in the Geisinger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28–1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk.”¹¹

¹⁰ Lazarus, B., et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*, JAMA INTERN. MED., published online 11 Jan. 2016.

¹¹ See Schoenfeld, A. and Deborah Grady. *Adverse Effects Associated with Proton Pump Inhibitors*, JAMA INTERNAL MEDICINE, published online 11 Jan. 2016.

214. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with propensity score-matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

215. Lazarus' data was confirmed and expanded by Yan Xie, et al.¹² Using Department of Veterans Affairs national databases to build a primary cohort of new users of PPI (n=173,321) and new users of histamine H2-receptor antagonists (H2 blockers; n=20,270), this study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

216. However, evidence of the connection of PPIs with AIN and CKD existed as early as 2007, and at no point did any one of the defendants seek to include appropriate warnings of renal dysfunction and/or renal disease in the labels for any of their PPI products.¹³

217. In Brewster and Perazella's review, they found that not only are PPIs "clearly associated with the development of AIN," most PPI patients they studied were "left with some

¹² Xie, Y., et al. *Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD*, J. AM. SOC. NEPHROL. (2016) 27: ccc-ccc.

¹³ Brewster, UC and MA Perazella. *Acute Kidney Injury Following Proton Pump Inhibitor Therapy*, KIDNEY INTERNATIONAL (2007) 71, 589-593.

level of chronic kidney disease. This CKD existed despite recovery of kidney function following PPI withdrawal.

218. Furthermore, Härmark, et al., noted that the Netherlands Pharmacovigilance Centre Lareb received reports of AIN with the use of omeprazole, pantoprazole, and rabeprazole, demonstrating that “AIN is a complication associated with all PPIs.”¹⁴

219. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved, despite the fact that studies have shown both a dose response relationship and greater hazard with longer periods of use. See Xie (2016) and Lazarus (2016) cited above.

220. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

221. From these findings, PPIs and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis (“AIN”), a sudden kidney inflammation that can result in mild to severe problems.

222. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

223. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

224. CKD describes a slow and progressive decline in kidney function that is manifested by fibrotic changes that occur in the functional unit of the kidney, known as the

¹⁴ Härmark, L., et al. *Proton Pump Inhibitor-Induced Acute Interstitial Nephritis*, BRIT. J. OF CLIN. PHARMACOLOGY (2007) 64(6): 819-23.

“neuron”. Such fibrotic changes can be accompanied by atrophy and loss of nephrons, which as it progresses can result in ESRD. As the kidneys lose their ability to function properly, waste products that normally are filtered from the blood by the kidney can build to dangerously high levels resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

225. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can typically be treated early in the course of disease, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals. In failing to warn physicians and consumers of this clear connection, the defendants, and each of them, prevented physicians from making informed choices to stop the offending drug, in this case the Nexium (esomeprazole) product ingested by the plaintiff herein.

226. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

227. Upon information and belief, this failure to warn was a deliberate effort by the defendants, individually and collectively, to continue to reap profits from its blockbuster PPI products from at least 1989 when Prilosec was first approved up through the present day

228. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with PPI use through the following acts or omissions:

229. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite also having evidence from its non-clinical studies that the kidneys of exposed test animals showed pathological changes consistent with acute and chronic kidney disease during the early phase testing, and instead

determined that the laboratory animals (rats, mice, dogs, rabbits) were suffering from some species-inherent form of chronic kidney disease (“chronic progressive nephropathy” or “CPN”) rather than a PPI-induced kidney disease.

230. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite also having evidence from its non-clinical studies that the kidneys of exposed test animals showed pathological changes consistent with acute and chronic kidney disease during the early phase testing, and instead determined that the laboratory animals (rats, mice, dogs, rabbits) were suffering from some species-inherent form of chronic kidney disease (“chronic progressive nephropathy” or “CPN”) rather than a PPI-induced kidney disease.

231. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite clinical evidence from published studies beginning as early as 1992 and continuing up through the early and mid-2000s that PPIs as a class were implicated in cases of acute kidney injury, including chronic kidney disease. This despite the fact that over the many years of its sale and distribution of its PPIs recommendations were made by researchers published in the peer reviewed scientific literature that further testing and elucidation of mechanism be performed by the pharmaceutical industry.

232. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite clinical evidence from published studies beginning as early as 1992 and continuing up through the early and mid-2000s that PPIs as a class were implicated in cases of acute kidney injury, including chronic kidney disease. This despite the fact that over the many years of its sale and distribution of its PPIs recommendations were made by researchers published in the peer reviewed scientific literature that further testing and elucidation of mechanism be performed by the pharmaceutical industry.

233. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite increasing reports of adverse

renal events, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease. Upon information and belief, Abbott affirmatively downplayed and/or underreported adverse renal events in an effort to hide kidney disease and its consequences from regulatory authorities, and the prescribers and consumers of PPI products.

234. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite increasing reports of adverse renal events, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

235. Upon information and belief, the Takeda Defendants affirmatively downplayed and/or underreported adverse renal events in an effort to hide kidney disease and its consequences from regulatory authorities, and the prescribers and consumers of PPI products.

236. Upon information and belief, Abbott, did not conduct renal safety testing of its product, despite signals observed in the non-clinical experimental studies, signals emerging from the published literature and from adverse event reports both from clinical trials and spontaneous reporting from the community, because Abbott knew that such testing would reveal renal abnormalities, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

237. Upon information and belief, the Takeda Defendants, did not conduct renal safety testing of its product, despite signals observed in the non-clinical experimental studies, signals emerging from the published literature and from adverse event reports both from clinical trials and spontaneous reporting from the community, because the Takeda Defendants knew that such testing would reveal renal abnormalities, including events of renal failure, both acute

and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

238. Upon information and belief the failure and omissions of Abbott and Takeda, individually and collectively, to conduct appropriate renal safety testing of its lansoprazole and dexlansoprazole PPIs was a deliberate and knowing effort by these defendants individually and collectively to hide renal safety issues from the regulatory authorities, prescribing physicians and the consuming public.

239. Upon information and belief, the failure and omissions of the Takeda Defendants and Abbott, individually and collectively, to conduct appropriate renal safety testing of its lansoprazole and dexlansoprazole PPIs was committed as part of a deliberate and conscious series of acts, and/or a conspiracy or scheme to reap continued profits from its blockbuster PPI products without disclosing renal safety issues all at the expense of human health, welfare and safety.

240. All Defendants, individually and collectively, concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD, ESRD, AKI or Renal Failure.

241. All Defendants, individually and collectively, concealed and continue to conceal their knowledge that PPI users should undergo routine laboratory testing to monitor renal function and should discontinue PPI use at the first sign of abnormal findings. Defendants never warned the medical community in the United States that renal function should be monitored and that PPIs should be discontinued immediately at the first sign of an abnormality and still do not warn of this

242. All Defendants, individually and collectively, concealed this knowledge despite the fact that they knew that immediate removal of the offending drug was critical as the first line treatment of a drug induced nephrotoxicity or renal injury and that this swift action was necessary to avoid long term, chronic and irreversible kidney damage.

243. Furthermore, all Defendants, individually and collectively, concealed this knowledge from the medical community in the United States despite warning physicians in Japan and elsewhere, as early as the 1990's, of the risk of interstitial nephritis, renal failure, and the need for vigilant monitoring of renal function via laboratory measurements.

244. All Defendants, individually and collectively, fraudulently and intentionally hired key opinion leaders to downplay the risks of PPIs, including the risk of serious and permanent kidney injury.

245. To this day, Defendants, individually and collectively, still do not warn US based physicians that they should be vigilantly monitoring renal function while patients are taking PPIs for signs of kidney injury including acute or chronic renal failure, acute or chronic interstitial nephritis or acute and/or chronic kidney injury.

246. To this day, Defendants, individually and collectively, deny that the use of PPIs poses a risk of chronic kidney disease.

247. To this day, Defendants, individually and collectively, deny that PPIs are a nephrotoxic medication.

248. To this day, Defendants, individually and collectively, fraudulently conceal the risks that PPIs pose to the kidney.

249. To this day, Defendants, individually and collectively, deny that PPI users should be have their renal function monitored for signs of renal injury.

250. As a result of Defendants' actions and inactions, Plaintiff was injured due to her ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

251. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

252. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

253. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to her new lifestyle.

254. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

282. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with the use of Defendants' PPI Products.

283. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

284. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

285. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

286. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

287. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

288. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

289. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

290. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

291. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

292. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

293. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

294. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

295. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

296. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

G. Defendants' Violations of Federal Law

297. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

298. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such

terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;

d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;

e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration of administration or application, and/or (d) route or method of administration or application;

f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;

g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;

h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;

i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;

j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;

k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;

l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;

m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and packaging materials do not meet the appropriate specifications;

n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;

o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;

p. Defendants' PPI Products violate 21 CFR § 310.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;

q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;

r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;

s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;

t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;

u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;

v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;

w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up";

x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant's PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;

y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated); and

z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ESTOPPEL FROM PLEADING AND TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

299. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

300. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

301. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

302. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

303. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

304. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have

exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

305. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

306. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

307. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

308. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

309. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's conditions.

310. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

311. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

312. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

CAUSES OF ACTION
COUNT I
STRICT PRODUCT LIABILITY

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

314. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including the Plaintiff.

315. At the time of Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

316. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

317. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

318. Defendants' PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiff.

319. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

320. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

321. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

322. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

323. At the time Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

324. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

325. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

326. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

327. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably dangerous to its intended users.

328. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

329. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

330. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

331. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

332. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hyper secretion, and the Defendants failed to adequately warn of said risk.

333. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

334. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

335. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

336. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

337. Plaintiff did not misuse or materially alter the PPI Products.

338. Defendants are strictly liable for Plaintiff' injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

339. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

340. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

341. These defects in Defendants' PPI Products were a substantial factor in causing Plaintiff's injuries.

342. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain

and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

343. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

COUNT II
STRICT PRODUCT LIABILITY –DESIGN DEFECT

344. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

345. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

346. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

347. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

348. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

349. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

350. At all times relevant, Defendants' PPI Products were expected to reach, and did reach, Plaintiff, without substantial change in the condition in which they were sold.

351. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

352. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

353. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

354. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

355. The risks of harm associated with the design of Defendants' PPI Products are higher than necessary.

356. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and the Plaintiff specifically was not aware of these risks, nor would she expect such risks.

357. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks

Products, or they were more dangerous than an ordinary consumer would expect.

358. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses;
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons;
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons;
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury specifically, the risk of kidney injuries.
- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products.

359. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

360. The PPI Products designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

361. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

362. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

363. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

364. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public.

365. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

366. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

367. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

368. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as

instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

369. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

370. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

371. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

372. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

373. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

374. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

375. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff injuries and damages.

376. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe.

377. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

378. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages.

379. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

380. The defective nature of the PPI Products was a substantial factor in causing the Plaintiff's injuries.

381. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

382. Defendants' conduct, as described herein, was extreme and outrageous.

383. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

COUNT III

STRICT PRODUCT LIABILITY – FAILURE TO WARN

384. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States.

385. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks.

386. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury.

387. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

388. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

389. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

390. The risks of PPI Products were not open and obvious.

391. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

392. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

393. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

394. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

395. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

396. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the risks were not open or obvious.

397. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

398. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

399. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

400. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

401. Had Plaintiff and/or Plaintiff's healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

402. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

403. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

404. Plaintiff and Plaintiff's healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

405. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

406. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

407. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

408. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

409. Defendants' conduct as described herein was a substantial factor in causing the Plaintiff's injuries.

410. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

411. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

412. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

COUNT IV **NEGLIGENCE**

413. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

414. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their

PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not cause users to suffer unreasonable, dangerous side effects.

415. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff's injuries and/or presented an unreasonably high risk of injury.

416. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;

- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
- k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
- l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
- m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
- n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;

- o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
- p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
- q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
- r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
- s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
- t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;
- u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
- v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
- w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;

- x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
- y. Failing to use due care under the circumstances; and
- z. Other such acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter.

417. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

418. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

419. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

420. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

421. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm (in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

422. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

423. Defendants acted in reckless disregard to public safety and well-being, including Plaintiff safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

424. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

425. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

426. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

COUNT V
NEGLIGENCE PER SE

427. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

429. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

430. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

431. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

432. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

433. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

434. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
NEGLIGENCE – FAILURE TO TEST

435. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

436. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

437. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

438. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

439. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

440. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

441. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary

health hazard to potential users such as the Plaintiff named herein.

442. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure and, in some cases, death caused by the use of the PPI Products.

443. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

444. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

445. Defendants are strictly liable for Plaintiff's injuries resulting from the Defendants' failure to test their PPI Products.

446. As a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and/or death; and economic damages incurred through the treatment for the renal failure and renal injuries and/or death caused by PPI Product use.

COUNT VII **BREACH OF EXPRESS WARRANTY**

448. Plaintiff repeats, reiterates, and re-alleges each and every preceding allegation of this Complaint with the same force and effect as if fully set forth herein.

449. Defendants expressly warranted that their PPIs were safe for their intended use, ingesting the product, to treat the targeted indication, GERD (or heartburn), as set forth more fully herein.

450. At the time Defendants made the express warranties described herein, Defendants had knowledge of the manner in which PPIs were to be used—by ingestion, and the purpose for which the PPIs were to be used—to treat heartburn, and Defendants expressly warranted PPIs to be in all respects safe, effective, and proper for such manner and purpose of use.

451. Defendants' PPIs failed to conform to these express representations, including, but not limited to, the express representation that PPIs were safe for their intended use of ingesting the product to treat heartburn, and the express representation that PPIs posed no increased risk to individuals with "Renal Insufficiency," as set forth more fully herein.

452. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Administration Options" Section for the delayed-release capsule version of the product stated, "Capsule can be swallowed whole" or "Capsule can be opened and mixed with applesauce" for oral consumption. Additionally, the labeling stated the delayed-release capsule version of the product can be "opened and intact granules emptied into a syringe and delivered through the nasogastric tube." In short, Defendants' labeling expressly instructed users it was safe to use the delayed-release capsule version of the product by ingesting it.

453. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Administration Options" Section for the delayed-release oral suspension version of the product stated, "Mix contents of packet with 1 tablespoon (15 mL) of water, leave 2 to 3 minutes to thicken, stir and drink within 30 minutes." Additionally, the labeling stated the delayed-release oral suspension version of the product can be prepared as above and "inject[ed] through the nasogastric or gastric tube within 30 minutes." In short, Defendants' labeling expressly instructed users it was safe to use the delayed-release oral suspension version of the product by ingesting it.

454. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Adverse Reactions" Section contained a "Clinical Trials Experience" subsection, stating that the "safety" of the product had been evaluated for the treatment of "GERD" (heartburn), and that adverse side-effects had been noted including, but not limited to, diarrhea, headache, and somnolence. Notably, there is no mention whatsoever in the labeling's "Adverse Reactions" section of kidney/renal injury, not even in the subsection for "additional adverse reactions ... with an incidence <1%[.]" Additionally, the labeling specifically states "no new safety concerns" were raised by the clinical trials. Thus, Defendants' labeling expressly warranted by omission that the product was safe for the use of ingesting the product for treatment of heartburn with no increased risk of kidney injury.

455. In expressly warranting their product as safe for ingestion, Defendants expressly warranted that their product was safe for the user's internal organs, especially their kidneys, since kidney injuries did not appear in any of the labeling sections relating to clinically-studied adverse side effects, as set forth above.

456. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Special Populations" Section contained a sub-grouping for individuals with "Renal Insufficiency," under which the labeling stated: "No dosage adjustment necessary." Thus, Defendants expressly warranted the product as safe for its intended use of ingesting the product to treat heartburn *specifically* in patients who already had renal insufficiency, and who thus were at an even higher risk of developing serious kidney injury from PPI use.

457. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Special Populations" Section contained a sub-grouping for individuals with "Renal Insufficiency," under which the labeling stated: "The pharmacokinetics of [PPIs]

in patients with renal impairment are not expected to be altered relative to healthy volunteers as less than 1% of esomeprazole is excreted unchanged in urine.” Thus, Defendants expressly warranted the product as safe for its intended use of ingesting the product to treat heartburn *specifically* in patients who already had renal impairment, and who thus were at an even higher risk of developing serious kidney injury from PPI use.

458. In expressly warranting their product as safe for use *even* by individuals who had renal insufficiency or renal impairment, it naturally follows that Defendants expressly warranted their product as safe for use by individuals who did not have renal insufficiency or renal impairment.

459. In expressly warranting their product as safe for use *even* by individuals who had renal insufficiency or renal impairment, Defendants expressly warranted that using PPIs as intended—ingesting them to treat heartburn—carried no increased risk of serious renal (kidney) injury.

460. Defendants’ express warranties were part of the basis for Plaintiff’s PPI use, as Plaintiff relied on Defendants’ express warranties in deciding to use PPIs.

461. Defendants’ breached their express warranties as described herein because PPIs are not safe to ingest and, to the contrary, produce serious side effects to users’ internal organs, including their kidneys.

462. As a result of the foregoing breaches of express warranties, the Plaintiff herein was caused to suffer serious kidney injuries, as well as other severe and personal injuries that are permanent and lasting in nature, including physical pain and mental anguish, diminished enjoyment of life, a risk of future kidney injuries, a reasonable fear of future decline in kidney function, any and all life complications caused by Plaintiff’s existing kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above health consequences.

463. As a result of the foregoing breaches of express warranties, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment as compared with prior to Plaintiff's use of Defendants' PPI drugs.

COUNT VIII
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

464. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint with the same force and effect as if set forth fully herein.

465. Defendants, as large pharmaceutical corporations, are merchants with respect to the kind of goods that includes PPIs—pharmaceutics, and thus it is reasonably expected and assumed by purchasers of Defendants' products that Defendants' pharmaceutical products, including PPIs, are safe for their ordinary purpose of being ingested to treat a particular medical condition.

466. At all times herein mentioned, the Defendants manufactured, compounded, distributed, recommended, merchandized, advertised, promoted and sold PPIs for the ordinary purpose of ingesting PPIs to treat heartburn.

467. As merchants of PPIs, Defendants impliedly represented and warranted to the users of PPIs, including Plaintiff, that PPIs were of merchantable quality and safe for such ordinary purpose of ingesting PPIs to treat heartburn.

468. These aforementioned representations and warranties were false, misleading, and inaccurate because PPIs were unsafe, unreasonably dangerous, and were not of merchantable quality, consequently degrading Plaintiff's health.

469. PPIs were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition, and the products were expected to reach and did

without any substantial change in the condition in which they were sold.

470. Plaintiff and members of the medical community relied on Defendants' implied warranty of merchantability in deciding to use PPIs for the ordinary purpose of ingesting PPIs to treat heartburn.

471. Plaintiff reasonably relied upon the skill and judgment of Defendants with respect to whether PPIs were safe and fit for the ordinary purpose for which they were intended as described herein.

472. Defendants breached the aforesaid implied warranty of merchantability as PPIs were not fit for their ordinary purpose for which such goods are used, and in fact had an unreasonable risk of harm to internal organs, specifically, the kidneys.

473. Upon discovering the connection between Plaintiff's ordinary use of Defendants' PPIs and Plaintiff's resultant kidney injury, Plaintiff provided notice to Defendants of Defendants' breach of implied warranty of merchantability by filing this lawsuit.

474. As a result of the foregoing breach of implied warranty of merchantability, the Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

475. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

COUNT IX
NEGLIGENT MISREPRESENTATION

476. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

477. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

478. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

479. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation without any reasonable ground for believing them to be true.

480. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and Plaintiff's healthcare providers, as to the health risks and consequences of the use of their PPI Products.

481. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI

Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

482. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demand for, as well as the ultimate prescription, purchase and use of their PPI Products.

483. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

484. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

485. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

486. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain

and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

487. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

COUNT X
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant Abbott)

488. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

489. As a result of Defendant Abbott's research and testing, or lack thereof, Defendant Abbott blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that Defendant Abbott's PPIs were safe and effective for use.

490. As a result of Defendant Abbott's research and testing, or lack thereof, Defendant Abbott intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

491. Defendant Abbott had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

492. The information distributed to the public, the FDA, and the Plaintiff by Defendant Abbott, including but not limited to reports, press releases, advertising campaigns,

television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

493. The information distributed to the public, the FDA, and the Plaintiff by Defendant Abbott intentionally included representations that Defendant Abbott's PPIs were safe and effective.

494. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant Abbott intentionally included representations that Defendant Abbott's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

495. The information distributed to the public, the FDA, and the Plaintiff, by Defendant Abbott intentionally included representations that Defendant Abbott's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with PPIs.

496. The information distributed to the public, the FDA, and the Plaintiff, by Defendant Abbott intentionally included false representations that PPIs were not injurious to the health and/or safety of its intended users.

497. These representations were all false and misleading.

498. Upon information and belief, Defendant Abbott intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that PPIs were not safe for its intended use.

499. Defendant Abbott intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of PPIs, specifically but not limited to Defendant Abbott's PPIs not having dangerous and serious health and/or safety concerns.

500. That it was the purpose of Defendant Abbott in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the

public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

501. Defendant Abbott made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that PPIs were fit and safe for its intended use.

502. Defendant Abbott made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant Abbott's PPIs were fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

503. The Defendant Abbott made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant Abbott's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

504. That these representations and others made by Defendant Abbott were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

505. That these representations and others, made by Defendant Abbott, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant Abbott's PPIs.

506. The Defendant Abbott, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs to the public

at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

507. That Defendant Abbott willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant Abbott's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

508. Defendant Abbott, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

509. Defendant Abbott utilized direct to consumer advertising to market, promote, and/or advertise Defendant Abbott's PPIs.

510. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendant Abbott's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant Abbott's PPIs.

511. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs.

512. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant Abbott, nor could the Plaintiff with reasonable diligence have discovered the true facts.

513. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs, Plaintiff would not have purchased, used and/or relied on Defendant's PPIs.

514. That the Defendant Abbott's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

515. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

516. Defendant Abbott's conduct, as described herein, was extreme and outrageous. Defendant Abbott risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant Abbott made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

517. To this day, Abbott continues to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant Abbott's PPIs cause to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

FRAUD AND FRAUDULENT MISREPRESENTATION

(As to Defendant TPUSA)

518. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

519. Defendant TPUSA conducted research and used PPIs as part of its research.

520. As a result of Defendant TPUSA's research and testing, or lack thereof, Defendant TPUSA blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPUSA's PPIs were safe and effective for use.

521. As a result of Defendant TPUSA's research and testing, or lack thereof, Defendant TPUSA intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

522. Defendant TPUSA had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

523. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPUSA, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

524. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs was safe and effective.

525. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

526. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of Prevacid in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Prevacid.

527. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPUSA intentionally included false representations that Defendant TPUSA's PPIs was not injurious to the health and/or safety of its intended users.

528. These representations were all false and misleading.

529. Upon information and belief, Defendant TPUSA intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPUSA's PPIs was not safe for its intended use.

530. Defendant TPUSA intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPUSA's PPIs, specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

531. That it was the purpose of Defendant TPUSA in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPUSA's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Defendant TPUSA's PPIs.

532. Defendant TPUSA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPUSA's PPIs was fit and safe for its intended use.

533. Defendant TPUSA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPUSA's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

534. Defendant TPUSA made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TPUSA's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

535. That these representations and others made by Defendant TPUSA were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

536. That these representations and others, made by Defendant TPUSA, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPUSA's PPIs.

537. Defendant TPUSA, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

538. That Defendant TPUSA willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPUSA's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

539. Defendant TPUSA, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

540. Defendant TPUSA utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPUSA's PPIs.

541. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPUSA's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TPUSA's PPIs.

542. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs.

543. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPUSA, nor could the Plaintiff with reasonable diligence have discovered the true facts.

544. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

545. That Defendant TPUSA's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

546. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

547. Defendant TPUSA's conduct, as described herein, was extreme and outrageous. Defendant TPUSA risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPUSA made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

548. To this day, Defendant TPUSA continue to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPUSA's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

COUNT XII
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TPA)

549. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

550. Defendant TPA conducted research and used PPIs as part of its research.

551. As a result of Defendant TPA's research and testing, or lack thereof, Defendant TPA blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPA's PPIs was safe and effective for use.

552. As a result of Defendant TPA's research and testing, or lack thereof, Defendant TPA intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

553. Defendant TPA had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

554. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPA, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

555. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPA intentionally included representations that Defendant TPA's PPIs was safe and effective.

556. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TPA intentionally included representations that Defendant TPA's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

557. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPA intentionally included representations that Defendant TPA's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of Defendant TPA's PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Defendant TPA's PPIs.

558. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPA intentionally included false representations that Defendant TPA's PPIs was not injurious to the health and/or safety of its intended users.

559. These representations were all false and misleading.

560. Upon information and belief, Defendant TPA intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPA's PPIs was not safe for its intended use.

561. Defendant TPA intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPA's PPIs, specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

562. That it was the purpose of Defendant TPA in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPA's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Defendant TPA's PPIs.

563. Defendant TPA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPA's PPIs was fit and safe for its intended use.

564. Defendant TPA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPA's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

565. Defendant TPA made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Prevacid did not

present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant TPA's PPIs.

566. That these representations and others made by Defendant TPA were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

567. That these representations and others, made by Defendant TPA, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPA's PPIs.

568. Defendant TPA, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

569. That Defendant TPA willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPA's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

570. Defendant TPA, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

571. Defendant TPA utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPA's PPIs.

572. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPA's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TPA's PPIs.

573. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs.

574. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPA, nor could the Plaintiff with reasonable diligence have discovered the true facts.

575. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

576. That Defendant TPA's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

577. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

578. Defendant TPA's conduct, as described herein, was extreme and outrageous. Defendant TPA risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPA made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

579. To this day, Defendant TPA continue to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPA's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

COUNT XIII
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TDC)

580. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

581. Defendant TDC conducted research and used PPIs as part of its research.

582. As a result of Defendant TDC's research and testing, or lack thereof, Defendant TDC blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TDC's PPIs was safe and effective for use.

583. As a result of Defendant TDC's research and testing, or lack thereof, Defendant TDC intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

584. Defendant TDC had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

585. The information distributed to the public, the FDA, and the Plaintiff by Defendant TDC, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

586. The information distributed to the public, the FDA, and the Plaintiff by Defendant TDC intentionally included representations that Defendant TDC's PPIs was safe and effective.

587. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TDC intentionally included representations that Defendant TDC's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

588. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TDC intentionally included representations that Defendant TDC's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with PPIs.

589. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TDC intentionally included false representations that PPIs were not injurious to the health and/or safety of its intended users.

590. These representations were all false and misleading.

591. Upon information and belief, Defendant TDC intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TDC's PPIs were not safe for its intended use.

592. Defendant TDC intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of PPIs, specifically but not limited to Defendant TDC's PPIs not having dangerous and serious health and/or safety concerns.

593. That it was the purpose of Defendant TDC in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and

fitness for use of Defendant TDC's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

594. Defendant TDC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TDC's PPIs were fit and safe for its intended use.

595. Defendant TDC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TDC's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

596. Defendant TDC made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TDC's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

597. That these representations and others made by Defendant TDC were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

598. That these representations and others, made by Defendant TDC, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TDC's PPIs.

599. Defendant TDC, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TDC's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

600. That Defendant TDC willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TDC's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

601. Defendant TDC, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

602. Defendant TDC utilized direct to consumer advertising to market, promote, and/or advertise Defendant TDC's PPIs.

603. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TDC's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TDC's PPIs.

604. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TDC's PPIs.

605. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TDC, nor could the Plaintiff with reasonable diligence have discovered the true facts.

606. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

607. That Defendant TDC's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

608. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

609. Defendant TDC's conduct, as described herein, was extreme and outrageous. Defendant TDC risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TDC made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

610. To this day, Defendant TDC continue to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TDC's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

COUNT XIV
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TPC)

611. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

612. Defendant TPC conducted research and PPIs as part of its research.

613. As a result of Defendant TPC's research and testing, or lack thereof, Defendant TPC blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPC's PPIs was safe and effective for use.

614. As a result of Defendant TPC's research and testing, or lack thereof, Defendant TPC intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

615. Defendant TPC had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

616. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPC, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

617. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPC intentionally included representations that Defendant TPC's PPIs was safe and effective.

618. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TPC intentionally included representations that Defendant TPC's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

619. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPC intentionally included representations that Defendant TPC's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Defendant TPC's PPIs.

620. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPC intentionally included false representations that Defendant TPC's PPIs was not injurious to the health and/or safety of its intended users.

621. These representations were all false and misleading.

622. Upon information and belief, Defendant TPC intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPC's PPIs was not safe for its intended use.

623. Defendant TPC intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPC's PPIs, specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

624. That it was the purpose of Defendant TPC in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPC's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

625. Defendant TPC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPC's PPIs was fit and safe for its intended use.

626. Defendant TPC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPC's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

627. Defendant TPC made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TPC's

PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

628. That these representations and others made by Defendant TPC were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

629. That these representations and others, made by Defendant TPC, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPC's PPIs.

630. Defendant TPC, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

631. That Defendant TPC willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPC's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

632. Defendant TPC, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

633. Defendant TPC utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPC's PPIs.

634. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPC's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TPC's PPIs.

635. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs.

636. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPC, nor could the Plaintiff with reasonable diligence have discovered the true facts.

637. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

638. That Defendant TPC's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

639. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

640. Defendant TPC's conduct, as described herein, was extreme and outrageous. Defendant TPC risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPC made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

641. To this day, Defendant TPC continue to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPC's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

COUNT XV
GROSS NEGLIGENCE

1000. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States.

1001. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

1002. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which

proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XVI
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

1003. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

1004. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

1005. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, 815 ILCS 505/1.

1006. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

1007. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Prejudgment interest;
- d. Post-judgment interest;
- e. Awarding reasonable attorneys' fees;
- f. Awarding the costs of these proceedings; and
- g. Such other and further relief as this Court deems just and proper.

JURY DEMAND

TAKE NOTICE that the Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: November 14, 2019

Respectfully submitted,

/s/E. Samuel Geisler
E. Samuel Geisler (ARDC 6305996)
AYLSTOCK, WITKIN, KREIS &
OVERHOLTZ, PLLC
17 E. Main Street, Suite 200
Pensacola, Florida 32502
Tel: (850) 202-1010
Fax: (850) 772-9062
Email: SGeisler@awkolaw.com

-and-

Paul J. Pennock (*Pro hac vice* to be filed)
Weitz & Luxenberg P.C.
700 Broadway
New York, New York 10003
Phone: (212) 558-5549
Fax: (646)-293-6539
ppennock@weitzlux.com

ATTORNEYS FOR PLAINTIFF

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

RONALD SUMMERS

Plaintiff,

vs.

TAKEDA PHARMACEUTICALS U.S.A.,
INC.; TAKEDA PHARMACEUTICALS
AMERICA, INC.; TAKEDA
PHARMACEUTICAL COMPANY
LIMITED; TAKEDA DEVELOPMENT
CENTER AMERICAS, INC., f/k/a TAKEDA
GLOBAL RESEARCH & DEVELOPMENT
CENTER, INC.; TAP PHARMACEUTICAL
PRODUCTS, INC. f/k/a TAP HOLDINGS,
INC.; NOVARTIS CORPORATION,
NOVARTIS PHARMACEUTICALS
CORPORATION; NOVARTIS VACCINES
AND DIAGNOSTICS, INC.; NOVARTIS
INSTITUTES FOR BIOMEDICAL
RESEARCH, INC; NOVARTIS
CONSUMER HEALTH INC. d/b/a GSK;
GLAXOSMITHKLINE CONSUMER
HEALTHCARE HOLDINGS (US) LLC

Defendants.

CASE NO: 2019L005876

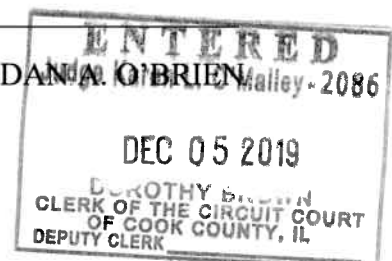
**This Motion Relates To The Cases
Consolidated on July 29, 2019**

[PROPOSED] ORDER GRANTING PLAINTIFFS' MOTION FOR
LEAVE TO FILE AMENDED COMPLAINTS

Plaintiffs' Motion for Leave to File Amended Complaints is **GRANTED**. The Amended Complaints at Law filed contemporaneously with this motion are hereby deemed as filed in each corresponding consolidated case.

SO ORDERED, this 6th day of ~~November~~ ^{December}, 2019.

HONORABLE JUDGE BRENDA A. O'BRIEN



FILED
3/16/2020 1:15 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

**IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION**

This Document Relates To:

JACQUELINE MEDIOUS-SANDERS

Plaintiff,

vs.

ABBOTT LABORATORIES; TAKEDA
PHARMACEUTICALS USA, INC.; TAKEDA
PHARMACEUTICALS AMERICA, INC.;
TAKEDA DEVELOPMENT CENTER
AMERICAS, INC. F/K/A TAKEDA GLOBAL
RESEARCH & DEVELOPMENT CENTER,
INC.; TAKEDA PHARMACEUTICAL
COMPANY LIMITED

Defendants.

CASE NO: 2019-L-006045

**Consolidated Case No.
2019-L-005876**

Hon. Brendan A. O'Brien

Calendar X

**ANSWER AND SEPARATE OR
AFFIRMATIVE DEFENSES OF
ABBOTT LABORATORIES TO
PLAINTIFF'S AMENDED
COMPLAINT**

**JURY DEMAND ENDORSED
HEREON**

COMES NOW, Abbott Laboratories, by and through its attorneys, answers Plaintiff's Amended Complaint ("Complaint") as follows:

NATURE OF THE ACTION

1. Plaintiff seeks compensatory damages, monetary restitution and all other available remedies as a result of injuries caused by Defendants' defective pharmaceutical products. Plaintiff makes the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts to date, regarding Defendants' prescription and over-the-counter Proton-Pump Inhibitor products (hereinafter together or individually, "the PPI Products" or "PPIs").

ANSWER: Abbott admits that Plaintiff seeks damages and other relief against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPIs.” Abbott denies that Plaintiff is entitled to judgment, damages, or relief of any kind and further denies the remaining allegations of paragraph 1.

2. The Plaintiff herein does not relinquish the right to move to amend her individual claims to seek any additional claims as discovery proceeds and facts and other circumstances may warrant.

ANSWER: Abbott states that the allegations of paragraph 2 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

3. As more particularly set forth herein, the Plaintiff maintains that the PPI Products are defective in design, dangerous to human health, unfit and unsuitable to be advertised, marketed and sold in the United States, and lack proper warnings associated with their use. This is a personal injury action against Defendants and their affiliates, subsidiaries, alter-egos, and/or joint venturers who were responsible for designing, researching, developing, testing, manufacturing, packaging, labeling, marketing, promoting, distributing, and/or selling the PPI Products, including, but not limited to Prevacid.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. To the extent a response is required, Abbott admits that Plaintiff has brought a personal injury action against the named defendants, including Abbott, with respect to medications that Plaintiff purports to define as “PPI Products” or “PPI’s.” Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott denies that it is liable to Plaintiff for any claims in any personal injury action and further denies any remaining allegations of paragraph 3 that are directed to it.

4. PPIs are a product approved by Food and Drug Administration (“FDA”) with

approved indications for reduction of gastric acid production in order to treat such conditions as duodenal ulcer and its recurrence, NSAID-associated gastric ulcers as well as gastroesophageal reflux disease (GERD), dyspepsia, acid peptic disease, and other hypersecretory conditions including Zollinger-Ellison Syndrome.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Because the remaining allegations of paragraph 4 are vague and ambiguous as applied to Abbott, they are denied.

5. As a result of the defective nature of PPIs hereafter alleged, persons who ingested this product, including the Plaintiff, have suffered and may continue to suffer from certain kidney injuries including chronic kidney disease ("CKD").

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's medical condition, and therefore denies them. Abbott denies the remaining allegations of paragraph 5.

6. Defendants, individually and collectively, as hereafter alleged, failed to conduct proper testing of their PPI products, design studies aimed at detecting renal dysfunction for which Defendants knew or should have known could occur with their PPI products, failed to properly warn physicians prescribing PPIs to monitor their patients for adverse renal events and to promptly discontinue said PPIs if signs of kidney dysfunction occurred, failed to properly monitor renal adverse events related to their PPIs in the post-marketing period and failed to bring to the attention of regulators, prescribing physicians and the consuming public a myriad of concerning reports received by the Defendants and reported in the peer-reviewed scientific literature.

ANSWER: Abbott denies the allegations of paragraph 6.

7. It is further alleged that Defendants, individually and collectively, purposely concealed (and continue to conceal to this day) their knowledge of PPIs' unreasonably dangerous effects on the kidneys from Plaintiff, prescribing physicians, including Plaintiff's prescribing physician, other consumers, and the medical community at large. Specifically, Defendants failed to adequately inform consumers and the prescribing medical community about the elevated risk of kidney injuries related to ingestion of PPIs, in particular ingestion for longer periods of time beyond those indicated periods of usage and/or in vulnerable populations such as the elderly and/or those persons who are at risk for kidney disease as a result of underlying illnesses and

comorbidities.

ANSWER: Abbott denies the allegations of paragraph 7.

8. In failing to warn prescribing physicians and the consuming public, including the Plaintiff, of the aforesaid dangers associated with their PPI products, prescribers and their patients were prevented from knowing that continued and prolonged use of PPIs could cause and/or contribute to severe and irreversible kidney injury and/or exacerbate underlying kidney disease in patients sustaining such kidney injury.

ANSWER: Abbott denies the allegations of paragraph 8.

9. It is further alleged that the Defendants, individually and collectively, failed to contraindicate PPIs for use by individuals who were already at an increased risk of kidney injury, and failed to contraindicate PPIs for concomitant use with other known nephrotoxic medications, such as NSAIDs, thereby compounding the potential for persons, such as the plaintiff, to suffer additional and repeated kidney insults followed by chronic and irreversible kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 9.

10. It is further alleged that the Defendants, individually and collectively, encouraged and promoted the use of PPIs beyond the indications approved by FDA, including the use of PPIs beyond the prescribed periods approved in the label, including pervasive advertising campaigns aimed at prescribers and the consuming public concerning the “little purple pill” for use with “frequent heart burn” and actively encouraging “daily use” of said PPIs when defendants knew that these products were not so indicated.

ANSWER: Abbott denies the allegations of paragraph 10.

11. As a result of Defendants’ individual and collective actions, inactions, omissions, and purposeful conduct, as hereafter alleged, Plaintiff was injured due to his ingestion of PPIs, and caused to suffer severe and permanent injuries as herein alleged and will continue to suffer chronic and irreversible injuries and damages as herein alleged. Plaintiff accordingly seeks damages associated with said injuries and damages.

ANSWER: Abbott denies the allegations of paragraph 11.

PARTIES, JURISDICTION & VENUE

13. This Complaint is filed on behalf of the Plaintiff and/or Decedent’s listed here in, and if applicable, Plaintiff’s and/or Decedent’s spouses, children, decedents, Estates, Wards, beneficiaries and heirs.¹

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions

¹ Plaintiff’s Complaint omits paragraph 12.

to which no response is required. To the extent a response is required, Abbott admits that Plaintiff has brought a personal injury action against the named defendants. Abbott denies any remaining allegations of paragraph 13 that are directed to it.

14. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this court has in personam jurisdiction over the Defendants, because Defendants are present in the State of Illinois such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States and that its principal place of business is in the State of Illinois. Abbott denies the remaining allegations of paragraph 14.

15. This Court has personal jurisdiction over Defendants, pursuant to, and consistent with, Illinois' long-arm statute (735 ILCS 5/2-209) and the Constitutional requirements of Due Process in that Defendants acting through agents or apparent agents, committed one of more of the following:

- a. Defendants transacted business in the State of Illinois, 735 ILCS 5/2-209(a)(1);
- b. Defendants made or performed a contract or promise substantially connected within this state, 735 ILCS 5/2-209(a)(7);
- c. Defendants do business in and within Illinois, 735 ILCS 5/2-209(b)(4); and;
- d. Requiring Defendants to litigate this claim in Illinois does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States and that its principal place of business is in the State of Illinois. Abbott denies the remaining allegations of paragraph 15, including all subparts.

16. Defendants marked, promoted, and sold PPI Products in this State and in Cook County in particular. Additionally, Defendant Abbott Laboratories has its place of business in Abbott Park, Illinois along with the following Takeda entities that maintain their place of business in Deerfield, Illinois: Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited (“TPC”). These entities developed, researched, tested, and designed their respective PPI Products within or immediately surrounding Cook County. These ties represent a lasting, significant connection to this venue. Accordingly, venue is appropriate before this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, it has been involved in the marketing and/or promotion of Prevacid® in each of the States and that its principal place of business is in the State of Illinois. Abbott lacks knowledge or information sufficient to form a belief as to the truth of allegations directed to other parties and therefore denies them. Abbott denies the remaining allegations of paragraph 16.

17. Plaintiff, respectively, alleges an amount in controversy in excess of the minimal jurisdictional limits of this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to seek an amount in controversy that exceeds the jurisdictional limits of this Court. Abbott denies the remaining allegations of paragraph 17.

I. PLAINTIFF

18. Plaintiff, Jacqueline Medious-Sanders, resides in Cook County, Illinois and resided in Cook County, Illinois at all times relevant.

- a. Plaintiff, Jacqueline Medious-Sanders ingested the following PPI products sold by the Defendants from at least approximately January 2003 to June 2008: Prevacid.
- b. As a direct and proximate result of Plaintiff’s use of the PPI(s), Prevacid, Plaintiff has suffered and was treated for Chronic Kidney Disease (“CKD”) in approximately January 2010 with related sequelae.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPIs or medical condition, and therefore denies them. Abbott denies the remaining allegations of paragraph 18, including all subparts.

19. Plaintiff alleges, as set forth more fully below, that she developed CKD as a direct and proximate cause of her ingestion of Defendants' defective PPI product, Prevacid, and that she was prevented from obtaining her best chance of cure based upon ongoing and repeated exposures to Defendants' PPI product.

ANSWER: Abbott denies the allegations of paragraph 19.

II. DEFENDANTS

19. Defendant Abbott Laboratories ("Defendant Abbott") is and, at all times relevant to this action, has been an Illinois Corporation having a principal place of business at 100 Abbott Park Rd., Abbott Park, IL. 60064.²

ANSWER: Abbott admits the allegations of paragraph 19.

20. As a part of their business and at all relevant times, Defendant Abbott has been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of prescription Prevacid (lansoprazole) products.

ANSWER: Abbott admits that, at various times in the past, Abbott researched, tested, packaged, marketed and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott specifically denies that it manufactured Prevacid® and further denies the remaining allegations of paragraph 20.

21. Defendant Abbott manufactures and markets Prevacid in the United States.

ANSWER: Abbott admits that, at various times in the past, Abbott marketed and/or promoted Prevacid® in the United States but specifically denies that it manufactured Prevacid®, and denies any remaining allegations of paragraph 21.

² Plaintiff's Complaint contains two paragraphs numbered 19.

22. Defendant Abbott has transacted and conducted business related to Prevacid in each of the States and Territories of the United States.

ANSWER: Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in each of the States and the District of Columbia. Abbott denies the remaining allegations of paragraph 22.

23. Defendant Abbott has derived substantial revenue from Prevacid in each of the States and Territories of the United States.

ANSWER: Abbott admits that it has received revenue from the sale of Prevacid® in the United States. Abbott states that the phrase “substantial revenue” is vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Abbott denies any remaining or inconsistent allegations of paragraph 23.

24. Defendant Abbott has expected or should have expected its acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related to Prevacid.

ANSWER: Abbott states that the phrases “its acts,” “consequence,” and “substantial revenue” are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph pertaining to same, and therefore denies them. Abbott denies the remaining allegations of paragraph 24.

25. Defendant Takeda Pharmaceuticals USA, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 25, and therefore denies them.

26. Defendant Takeda Pharmaceuticals America, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, Ill 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 26, and therefore denies them.

27. Defendant Takeda Pharmaceuticals, LLC, at all times relevant to this action, has been wholly owned by Defendant Takeda Pharmaceuticals America, Inc. and Defendant Takeda Pharmaceuticals USA, Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 27, and therefore denies them.

28. Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. is and, at all times relevant to this action, has been an Illinois corporation having a principal place of business at One Takeda Parkway, Deerfield, IL 60015.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 28, and therefore denies them.

29. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuoku, Osaka, Japan.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of

paragraph 29, and therefore denies them.

30. Defendant Takeda Pharmaceutical Company Limited is and, at all times relevant to this action, has been the parent/holding company of Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 30, and therefore denies them.

31. Defendant Takeda Pharmaceutical Company Limited, at all times relevant to this action is a parent company and has exercised and exercises dominion and control over Defendant Takeda Pharmaceuticals USA, Inc. and Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center Inc.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 31, and therefore denies them.

32. Defendant Takeda Pharmaceuticals USA, Inc., Defendant Takeda Pharmaceuticals America, Inc., Defendant Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Defendant Takeda Pharmaceutical Company Limited are referred herein collectively as “Takeda Defendants.”

ANSWER: Abbott states that the allegations of this paragraph do not require a response. If a response is required, Abbott admits that Plaintiff refers to Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc. and Takeda Pharmaceutical Company Limited as “Takeda Defendants.” Abbott denies any remaining allegations of paragraph 32.

33. Each of the Takeda Defendants was the agent and employee of the other Takeda Defendants and, in doing the things alleged, was acting within the course and scope of such agency and employment and with the other Takeda Defendants’ actual and implied permission, consent,

authorization and approval.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 33, and therefore denies them.

34. As a part of their business and at all relevant times, the Takeda Defendants have been involved in the design, research, manufacture, testing, advertisement, promotion, marketing, sale and distribution of Dexilant (dexlansoprazole), Prevacid, Prevacid 24HR and Protonix products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 34, and therefore denies them.

35. The Takeda Defendants, in collaboration amongst themselves, designed and developed the Prevacid and Prevacid 24HR products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 35, and therefore denies them.

36. Defendant Takeda Pharmaceuticals USA, Inc. is the holder of approved NDAs 020406, 021428 and 021281 for Prevacid.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 36, and therefore denies them.

37. The Takeda Defendants manufacture and market each of these prescription

Prevacid formulations in the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 37, and therefore denies them.

38. The Takeda Defendants manufacture and market each of these Prevacid 24HR formulations in the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 38, and therefore denies them.

39. The Takeda Defendants have transacted and conducted business related to PPI Products in each of the States and Territories of the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 39, and therefore denies them.

40. The Takeda Defendants have derived substantial revenue from PPI Products in each of the States and Territories of the United States.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 40, and therefore denies them.

41. The Takeda Defendants have expected or should have expected their acts to have consequence within each of the States and Territories of the United States, and derived substantial revenue from interstate commerce in each of the States and Territories of the United States related

to PPI Products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 41, and therefore denies them.

42. Defendants are each multinational Fortune 500 companies that have significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them. Defendants have derived revenue from the sale of their respective PPI Product(s) in each of the States and Territories of the United States, including in this County.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 42 at this time, and therefore denies them. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

43. Defendants have significant contacts within this County such that they are subject to the personal jurisdiction of this Court.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that, at various times in the past, Abbott has been involved in the marketing and/or promotion of Prevacid® in the United States. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 43 at this time, because jurisdictional issues are dependent on the facts of each case. Abbott reserves the right to contest personal jurisdiction, as appropriate, in this case.

FACTUAL ALLEGATIONS

44. PPI Products are indicated for the treatment of the following conditions: GERD; dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 44 at this time, and therefore denies them.

45. PPI Products work by inhibiting the secretion of stomach acid. They shut down acid production of the active acid pumps in the stomach, thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action is outlined in the FDA-approved product labeling, which speaks for itself. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 45 at this time, and therefore denies them.

46. PPI Products are one of the most commercially successful groups of medication in the history of pharmaceutical sales in the United States. Upon information and belief, from 2003 to the present, PPIs have been one of the top ten best-selling and most dispensed forms of prescription medication in the United States each year.

ANSWER: Abbott states that the allegations of this paragraph are vague and ambiguous as written. As such, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 46, and therefore denies them.

47. As of 2009, approximately 21 million Americans used one or more prescription PPI Products, accounting for nearly 20% of the drugs' global sales and earning an estimated \$11 billion annually.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 47, and therefore denies them.

48. Between the period of 2008 and 2013, prescription PPI Products had sales of over \$50 billion with approximately 240 million units dispensed.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 48, and therefore denies them.

49. According to the 2011–2012 National Health and Nutritional Examination Survey, 7.8% of US adults had used prescription PPI Products within the last 30 days.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 49, and therefore denies them.

50. As early as October 1992, researchers from the University of Arizona Health Sciences Center led by Stephen Ruffenach published the first article reporting PPI usage associated with kidney injury in The American Journal of Medicine.

ANSWER: Abbott admits that Dr. Stephen Ruffenach and other researchers from the University of Arizona Health Sciences Center published an article in the American Journal of Medicine in 1992 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 50.

51. Since 1992, there have been numerous adverse case reports and scientific studies published in medical journals and reported by physicians and scientists, as well as adverse reports from national adverse drug registries, which document an association between use of PPI Products and the occurrence of kidney injuries such as AIN, AKI, ARF CKD and ESRD.

ANSWER: Abbott states that the allegations of paragraph 51 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

52. Since 1992, numerous case repots [*sic*] have been published in the medical literature documenting an association between the use of PPI Products and the development of AIN amongst patients.

ANSWER: Abbott states that the allegations of paragraph 52 are vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

53. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI Product use, by way of AIN, left most patients "with some level of chronic kidney disease."

ANSWER: Abbott admits that researchers from the Yale School of Medicine published an article in the International Society of Nephrology's Kidney International in 2006 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 53.

54. In 2007, F. Sierra et al. published an article in the Journal of Alimentary Pharmacology and Therapeutics, titled, "Systematic review: proton pump inhibitor-associated acute interstitial nephritis." The researchers concluded that long-term use of proton pump inhibitors is associated with interstitial nephritis.

ANSWER: Abbott admits that Dr. F. Sierra and others published an article in the Journal of Alimentary Pharmacology and Therapeutics in 2007 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 54.

55. In February 2007, Harmark et al. published their findings in the British Journal of Clinical Pharmacology that AIN could be induced by a variety of available PPI Products and was indicative of a class-effect and that this finding was further supported by adverse event data from the World Health Organization Collaborating Centre for International Drug Monitoring, "where PPI-induced AIN is disproportionately present in the database." Harmark et al., Proton-pump inhibitor-induced acute interstitial nephritis, BJ Clin. Pharm. (2007).

ANSWER: Abbott states that Dr. Harmark and others published an article in the British Journal of Clinical Pharmacology in 2007 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 55.

56. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a Citizen's Petition with the FDA seeking the addition of safety information concerning several risks associated with PPI Product usage, including, among others, PPI-induced AIN.

ANSWER: Abbott admits, on information and belief, that on August 23, 2011, Public Citizen filed a petition with the FDA requesting that additional warnings be added to the labeling of PPI products. Abbott denies the validity of this citizen's petition and further denies the

remaining allegations of paragraph 56.

57. According to the Public Citizen petition, at the time of the filing there was “no detailed risk information on any PPI for this adverse effect.”

ANSWER: Abbott admits, on information and belief, that the Public Citizen petition filed with the FDA on August 23, 2011 stated that “[i]nformation regarding the potential for drug-induced acute interstitial nephritis, seen in at least 60 case reports, should be included in the appropriate section. There is currently no detailed risk information on any PPI for this adverse effect.” Abbott denies the validity of this citizen’s petition and further denies the remaining allegations of paragraph 57.

58. On October 31, 2014, more than three years after Public Citizen’s petition, the FDA responded by requiring consistent labeling regarding the risk of AIN on all prescription PPI Products.

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen’s petition by concluding that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 58.

59. The FDA found that there was “reasonable evidence of a causal association” and therefore, concluded “that the prescription PPI labeling should be consistent with regard to this risk[.]”

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen’s petition by stating that “[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling,” labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 59.

60. In December of 2014, all labels for prescription PPI Products were required to

include the following information:

Acute interstitial nephritis has been observed in patients taking PPIs including [Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 60, and therefore denies them.

61. To this date, Defendants' over-the-counter PPI Products do not include a warning or any risk information about AIN.

ANSWER: Abbott states that the allegations of paragraph 61 do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted any "over-the counter PPI Products" as alleged and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to the identification of the products at issue in this paragraph. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

62. The current warning contained on prescription PPI Products regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

ANSWER: Abbott denies the allegations of paragraph 62.

63. Defendants have also failed to adequately inform physicians, and other healthcare providers such as pharmacists, and consumers regarding the risk of AIN and the use of over-the counter PPI Products.

ANSWER: Abbott denies the allegations of paragraph 63.

64. PPI Products and/or their metabolites – substances formed via metabolism – have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate AIN, a sudden kidney inflammation that can result in mild to severe problems.

ANSWER: Abbott denies that that the mechanism by which drugs may cause AIN has

been established. Abbott denies any remaining or inconsistent allegations of paragraph 64.

65. PPI-induced AIN can be difficult to diagnose, with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea and weakness.

ANSWER: Abbott admits that not every patient diagnosed with AIN presents with a fever.

Abbott denies any remaining or inconsistent allegations of paragraph 65.

66. Use of PPI Products may lead to subclinical AIN according to multiple studies, including but not limited to:

- a. Lazarus B, Chen Y, Wilson FP, et al. *Proton Pump Inhibitor Use and the Risk of Chronic Kidney Disease*. 176 JAMA INTERNAL MED. 238 (2016); and
- b. DG Moledina & MA Perazella, *Proton Pump Inhibitors and CKD*, 27 J. AM. SOC. NEPHROL. 2926 (2016).

ANSWER: Abbott admits that the publications referenced in this paragraph are in the published literature and state that these publications speak for themselves. Abbott denies that the mechanism by which drugs may cause AIN has been established and further denies any remaining or inconsistent allegations of paragraph 66.

67. AIN's slow presentation can cause significant damage over time without those affected exhibiting acute symptoms.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott lacks knowledge or information sufficient to form a belief as to the truth the remaining allegations of paragraph 67, and therefore denies them.

68. Where AIN is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AIN can lead to Chronic Kidney Disease and End Stage Renal Disease requiring the patient to undergo permanent dialysis, kidney transplant or, in some cases, death.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure. Abbott lacks knowledge or information

sufficient to form a belief as to the remaining allegations of paragraph 68, and therefore denies them.

69. While AIN can be treated, once AIN has progressed to CKD it is incurable and can only be managed.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies that Prevacid® causes chronic kidney disease. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 69, and therefore denies them.

70. Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly.

ANSWER: Abbott denies that Prevacid® causes acute kidney injury or renal failure. Abbott admits that Acute Kidney Injury is characterized by acute and sudden renal failure by which the kidneys fail to filtrate properly. Abbott denies any remaining allegations of paragraph 70.

71. Studies indicate that those using PPI Products are at a more than 2.5 times greater risk than the general population to suffer AKI.

ANSWER: Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and denies the allegations of paragraph 71.

72. Studies also indicate that those who develop AIN are at a significant risk of AKI, even though they may not obviously exhibit kidney dysfunction.

ANSWER: Abbott states that the term “studies” is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth, and therefore denies them. Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott denies any remaining allegations of paragraph 72.

73. Currently, the product labeling for PPI Products, both prescription and over-the-counter, does not contain any warning regarding the increased risk of AKI.

ANSWER: Abbott admits, on information and belief, that Prevacid®'s product labeling does not explicitly reference AKI as defined in the Plaintiff's Complaint. Abbott further denies any remaining or inconsistent allegations of paragraph 73.

74. Where AKI is subclinical, it can persist for months before a patient realizes their injury. By that time, their untreated AKI can lead to CKD and ESRD.

ANSWER: Abbott denies the allegations of paragraph 74.

75. Chronic Kidney Disease is the gradual loss of kidney function. Kidneys filter Waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

ANSWER: Abbott admits that chronic kidney disease is the gradual loss of kidney function. Abbott denies that Prevacid® causes chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 75.

76. CKD can ultimately progress to End Stage Renal Disease in which total kidney function is lost and patients must either undergo dialysis or have a kidney transplant to survive.

ANSWER: Abbott admits that chronic kidney disease can, but does not always, lead to the development of end stage renal disease. Abbott denies that Prevacid® cause chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 76.

77. In January 2016, a study published in the Journal of the American Medical Association found that use of PPI Products was independently associated with a 20 – 50% higher risk of CKD.

ANSWER: Abbott admits that a study was published in the Journal of the American Medical Association in January 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease and further denies any remaining or inconsistent allegations of paragraph 77.

78. In February 2016, a study published in the Journal of the American Society of Nephrology found that “exposure to PPI is associated with increased risk of development of CKD, progression of kidney disease, and risk of ESRD.”

ANSWER: Abbott admits that a study was published in the Journal of the American Society of Nephrology in February 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease, progression of kidney disease, or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 78.

79. In April 2016, a study published in the Journal of Nephrology suggested that the development of and failure to treat AIN could lead to CKD and ESRD, which requires dialysis or kidney transplant to manage. Analyses of the study were adjusted for age, sex, race, baseline eGFR, cigarette smoking, BMI, systolic blood pressure, diabetes, a history of cardiovascular disease, antihypertensive medication use, anticoagulant medication use, statin, aspirin and NSAID use. Across all groups, “each of these sensitivity analyses showed a consistent association between PPI use and a higher risk of CKD.”

ANSWER: Abbott admits that a study was published in the Journal of Nephrology in April 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 79.

80. CKD is often a slow progressive decline in kidney function that may result in ESRD. As the kidneys lose their ability to function properly, wastes can build to high levels in the blood resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

ANSWER: Abbott denies the allegations characterizing chronic kidney disease in paragraph 80 and further denies that Prevacid® causes chronic kidney disease or end stage renal failure.

81. PPI Products have also been shown to cause CKD independent of, and in the absence of, an intervening AKI or AIN event, even where the AKI or AIN is subclinical. For example, the results of a 2017 epidemiologic study “showed a significant association between PPI use and chronic renal outcomes including incident CKD, CKD progression, and ESRD in the absence of intervening AKI.” Yan Xie et al., Long-Term Kidney Outcomes among Users of Proton

Pump Inhibitors without Intervening Acute Kidney Injury, 91 Kidney Int'l 1482 (2017).

ANSWER: Abbott admits that a study was published in the Kidney International in 2017 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 81.

82. To date, the labeling for Defendants' PPI Products lack adequate risk information about CKD.

ANSWER: Abbott denies the allegations of paragraph 82.

83. Users of PPI Products will, and have, experienced worse GERD, or acid reflux, upon ceasing PPI Product use, evidencing that PPI Products can lead to physical dependency and/or the worsening of symptoms upon removal of the PPI therapy.

ANSWER: Abbott denies the allegations of paragraph 83.

84. The worsening of GERD or acid reflux after withdrawal of PPI Products has been characterized by scientists as "rebound acid hypersecretion" and is characterized by an increase in acid secretion with the withdrawal of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 84.

85. This phenomenon was first identified during preclinical animal studies on rats treated with omeprazole/Prilosec.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no response by Abbott is required. If a response is required, Abbott specifically denies that it marketed and/or promoted "omeprazole/Prilosec" and further states that the remaining allegations of this paragraph are vague and ambiguous, especially as to "phenomenon." Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 85, and therefore denies them.

86. Because PPI Products work by preventing the acidification of the stomach's contents by blocking the proton pumps of the stomach, the body may react by compensating with increased production of gastrin, a hormone that stimulates secretion of gastric acid. Consequently, when users discontinue treatment with PPI Products, their bodies' acid production increases

beyond their pre-PPI treatment levels.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 86.

87. The increase in acid production after discontinuation of PPI Products caused and will continue to cause Plaintiff significant harm and a dependency on PPI Products.

ANSWER: Abbott denies the allegations of paragraph 87.

88. After Plaintiff's discontinuation of PPI Products, increased acid production to a level above that which existed before treatment with PPI Products was initiated has caused and will cause Plaintiff to treat GERD as a more severe condition than that which existed when PPI Products were initiated.

ANSWER: Abbott denies the allegations of paragraph 88.

89. Several studies have shown that treatment with PPI Products induces acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment is withdrawn in healthy individuals who have never before experienced heartburn or related symptoms.

ANSWER: Abbott states that the term "studies" is vague and ambiguous. Therefore, Abbott lacks knowledge or information sufficient to form a belief as to their truth of the allegations of paragraph 89 and therefore denies them.

90. Due to rebound hypersecretion, patients are unable, in many instances, to cease use of PPI Products, despite choosing and wanting to do so after learning of the risks of using PPI Products, including kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 90.

91. To date, the labeling for the Defendants' respective PPI Products contains no information regarding rebound acid hypersecretion or information that would assist healthcare providers and/or patients who suffer from this after ceasing to use PPI Products.

ANSWER: Abbott denies the allegations of paragraph 91.

92. Despite the fact that PPI Products lead to an increased risk of such severe injuries as outlined herein, several safer alternatives have been and are available, including but not limited to:

a. The use of over-the-counter calcium carbonate tablets that have been available

- since the 1930s, such as Maalox and Tums; and/or
- b. The use of histamine H2-receptor antagonists (also known as “H2 Blockers”) that were developed in the late 1960s. H2 Blockers act to prevent the production of stomach acid, work more quickly than PPI Products and are prescribed for the same indications as PPI Products. Examples of H2 Blockers include Zantac, Pepcid and Tagamet. H2 Blockers are not associated with an increased risk of kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 92, including all subparts.

93. In spite of their commercial success and global popularity, up to 70% of PPI Products may be used inappropriately for indications or durations that were never tested or approved. D. Marks, *Time to Halt the Overprescribing of Proton Pump Inhibitors*, THE PHARMACEUTICAL JOURNAL (Aug. 8, 2016).

ANSWER: Abbott admits that Dr. Marks published an article in The Pharmaceutical Journal in 2016 and states that the article speaks for itself. Abbott denies any remaining allegations of paragraph 93.

94. Consumers, including Plaintiff, who have used Defendants’ PPI Products for the treatment of increased gastric acid have and had several alternative safer treatments available and have not been adequately warned about the significant risks and lack of benefits associated with use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 94.

95. The use of PPI Products for time periods longer than those tested or approved is a direct consequence of Defendants’ (1) failure to adequately and specifically warn patients and healthcare providers as to the appropriate length of usage; (2) failure to provide adequate, clear and accurate marketing materials regarding appropriate usage of PPI Products and the appropriate and approved indications; and (3) engaging in off-label promotion of their respective PPI Products for indications that were not approved, and upon which Plaintiff and their respective prescribing physicians relied upon when making prescribing decisions.

ANSWER: Abbott denies the allegations of paragraph 95.

96. As a result of the defective nature of Defendants’ PPI Products, persons who ingested Defendants’ PPI Products have been exposed to significant risks stemming from unindicated and/or long-term usage, even when used as directed and/or prescribed by a physician or healthcare professional.

ANSWER: Abbott denies the allegations of paragraph 96.

97. Consumers, including Plaintiff, who have used Defendants’ PPI Products have suffered from severe kidney injuries including, but not limited to, AIN, AKI, CKD and ESRD.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 97.

98. Consumers, including Plaintiff, who have used Defendants' PPI Products have suffered from a worsening of acid-related symptoms like heartburn, acid regurgitation and dyspepsia once treatment with Defendants' PPI Products was withdrawn and have developed and suffered from a physical dependence on PPI treatment.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of Prevacid® or Plaintiff's medical conditions, and therefore denies them. Abbott denies the remaining allegations of paragraph 98.

194. From as early as the 1980s up through and including the present day, there have been post-marketing safety reports received by each of these defendants directly and in the form of published scientific and medical peer-reviewed literature case reports, case series, observational studies and meta-analyses that demonstrate that PPIs as a class cause kidney injuries, including, inter alia, AIN, AKI, CKD, ESRD and/or renal failure (acute and chronic).³

ANSWER: Abbott denies the allegations of paragraph 194.

195. AIN is a sub-type of AKI that manifests specifically as inflammation in the interstitium and tubules, structures that are contained within the nephron, also known as the "functional unit" of the kidney. If left unchecked or if treated insufficiently, AIN can progress to a chronic state, i.e., Chronic Interstitial Nephritis, that in turn can progress to downstream effects of CKD and ESRD, especially if the offending agent, i.e., PPI products, are not withdrawn.

ANSWER: Abbott admits that AIN is a subtype of AKI. Abbott denies the remaining allegations of paragraph 195.

196. In October of 1992, three years after the FDA's initial PPI approval, researchers from the University of Arizona Health Sciences Center, led by Stephen Ruffenach, published the first article associating PPI usage with kidney injuries in The American Journal of Medicine, followed by years of reports from national adverse drug registries describing this association. In

³ Plaintiff's Complaint omits paragraph 99 through 193.

1997, David Badov, et al., described two further case studies documenting the causal connection between omeprazole and interstitial nephritis in the elderly.

ANSWER: Abbott admits that the referenced studies appear in the published literature and states that the articles speak for themselves. Abbott denies any remaining or inconsistent allegations of paragraph 196.

197. Between 1995 and 1999, Nicholas Torpey, et al. conducted a single-center retrospective analysis of renal biopsy results from 296 consecutive patients to determine the etiology of acute tubule-interstitial nephritis (TIN). Acute AIN was identified in 24 (8.1%) biopsies. Eight out of fourteen cases with presumed drug-related AIN could be attributed to the PPIs omeprazole and lansoprazole.

ANSWER: Abbott admits that the analysis referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 197.

198. Defendants, individually and collectively, responsible for post-marketing surveillance, knew or should have known that between 1992 and 2004 more than 23 cases of biopsy-proven AIN secondary to omeprazole (Prilosec) had been reported.

ANSWER: Abbott states that the allegations of paragraph 198 are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

199. In 2004, Defendants, individually and collectively, knew or should have known of 8 biopsy-proven cases reported from Norwich University Hospital in the United Kingdom.

ANSWER: Abbott states that the allegations of paragraph 199 are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

200. International organizations also recognized the danger posed by PPIs to kidney health, finding both AIN and insidious renal failure resulting from PPIs. In 2006, Professor Ian Simpson and his team at the University of Auckland published an analysis of the clinical features of 15 patients with AIN and acute renal failure from PPI over three years. In all patients, the tie-course of drug exposure and improvement of renal function on withdrawal suggested the PPI were causal. "Although four patients presented with an acute systemic allergic reaction, 11 were asymptomatic with an insidious development of renal failure."

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Takeda further denies the remaining allegations of paragraph 200.

201. Furthermore, in the New Zealand study, Defendants, individually and collectively, knew or should have known that twelve of the reported cases were biopsy-proven cases of renal failure caused by tubulointerstitial injury.

ANSWER: Abbott states that the allegations of paragraph 201 are vague and ambiguous. Accordingly, Abbott lacks knowledge or information sufficient to form a belief as to the truth of those allegations, and denies them.

202. In 2006, Nimeshan Geevasinga, et al., found “evidence to incriminate all the commercially available PPIs, suggesting there is a class effect” with regard to PPI-induced AIN. “Failure to recognize this entity might have catastrophic long-term consequences including chronic kidney disease.” This study was the largest hospital-based case series on this issue and involved a retrospective case review of potential cases at two teaching hospitals as well as a review of registry data from the Therapeutic Goods Administration of Australia. The team identified eighteen cases of biopsy-proven PPI-induced AIN. The TGA registry data identified an additional thirty-one cases of “biopsy proven interstitial nephritis.” An additional ten cases of “suspected interstitial nephritis,” twenty cases of “unclassified acute renal failure,” and twenty-six cases of “renal impairment” were also identified. “All Five commercially available PPIs were implicated in these cases.”

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 202.

203. In 2006, the Center for Adverse Reaction Monitoring (CARM) in New Zealand, found that PPI products were the number one cause of AIN.

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 203.

204. In 2006, researchers at the Yale School of Medicine conducted a case series published in the International Society of Nephrology's Kidney International finding that PPI use, by way of AIN, left most patients “with some level of chronic kidney disease.”

ANSWER: Abbott admits that researchers from the Yale School of Medicine published an article in the International Society of Nephrology's Kidney International in 2006 and states that the article speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 204.

205. On August 23, 2011, Public Citizen, a consumer advocacy group, filed a petition with the FDA to add black box warnings and other safety information concerning several risks associated with PPIs including AIN, because, as alleged in the petition, there was "no detailed risk information on any PPI for this adverse effect."

ANSWER: Abbott admits, on information and belief, that on August 23, 2011, Public Citizen filed a petition with the FDA requesting that additional warnings be added to the labeling of PPI products. Abbott further admits, on information and belief, that the Public Citizen petition filed with the FDA on August 23, 2011 stated, for example, that "[i]nformation regarding the potential for drug-induced acute interstitial nephritis, seen in at least 60 case reports, should be included in the appropriate section. There is currently no detailed risk information on any PPI for this adverse effect." Abbott denies the validity of this citizen's petition and further denies the remaining allegations of paragraph 205.

206. In 2013, Klepser, et al. found that "patients with a renal disease diagnosis were twice as likely to have used a previous prescription for a PPI." Klepser's study called for increased recognition of patient complaints or clinical manifestations of renal disease in order to prevent further injury.

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 206.

207. Also in 2013, Sampathkumar, et al. followed four cases of PPI users, finding that AIN developed after an average period of four weeks of PPI therapy. Researchers further noted that "a high index of suspicion about this condition should prompt the physician to stop the drug, perform a renal biopsy if needed and start steroid therapy for halting a progressive renal disease."

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 207.

208. In 2014, New Zealand researchers conducted a nested case-control study using routinely collected national health and drug dispensing data in New Zealand to estimate the relative and absolute risks of acute interstitial nephritis resulting in hospitalization or death in users of PPIs. The study compared past use with current and ongoing use of PPIs, finding a significantly increased risk of acute interstitial nephritis for patients currently taking PPIs.

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 208.

209. On October 31, 2014, more than three years after Public Citizen's petition, the FDA responded by requiring consistent labeling regarding risk of AIN on all prescription PPIs.

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen's petition by stating that "[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling," labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 209.

210. The FDA noted "that the prescription PPI labeling should be consistent with regard to this risk" and that "there is reasonable evidence of a causal association."

ANSWER: Abbott admits, on information and belief, that on October 31, 2014, the FDA responded to Public Citizen's petition by stating that "[a]lthough nearly all prescription PPI products mention[ed] the risk of AIN in their labeling," labeling consistent across all prescription PPIs should be implemented describing the risk of AIN. Abbott denies the remaining allegations of paragraph 210.

211. In December of 2014, the labels of prescription PPIs were updated to read:

Acute interstitial nephritis has been observed in patients taking PPIs including

[Brand]. Acute interstitial nephritis may occur at any point during PPI therapy and is generally attributed to an idiopathic hypersensitivity reaction. Discontinue [PPI] if acute interstitial nephritis develops.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 211, and therefore denies them.

212. In a study conducted by Benjamin Lazarus, et al., published in JAMA, PPI use was associated with a higher risk of incident CKD.¹⁰ The authors leveraged longitudinal data from two large patient cohorts in the United States, the Atherosclerosis Risk in Communities study (n 1/4 10,482) and the Geisinger Health System (n 1/4 248,751), in order to evaluate the relationship between PPI use and the development of chronic kidney disease (CKD). Over a median of 13.9 years of follow-up in the Atherosclerosis Risk in Communities study, the incidence of documented CKD or end-stage renal disease was significantly higher in patients with self-reported use of prescription PPIs at baseline (adjusted hazard ratio 1.50, 95% confidence interval 1.14-1.96).

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 212.

213. “Consistent with prior studies, the authors also observed a significant association between baseline PPI use and acute kidney injury as defined by diagnostic codes (adjusted hazard ratio 1.64, 95% confidence interval 1.22-2.21). The results were then validated in the Geisinger Health System cohort using prescription data to define baseline PPI use and laboratory data to define the CKD outcome, defined as sustained outpatient estimated glomerular filtration rate the validation cohort also suggest a possible dose-response relationship between PPI use and CKD risk, with higher risk observed in patients prescribed a PPI twice daily at baseline (adjusted hazard ratio 1.46, 95% confidence interval 1.28-1.67). Despite the limitations inherent in observational studies, the robustness of the observations in this large study suggests a true association between PPI use and increased CKD risk.”

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 213.

214. In quantifying the association between PPI use and CKD, Lazarus found that PPI use was associated with incident CKD in unadjusted analysis (hazard ratio [HR], 1.45; 95% CI, 1.11-1.90); in analysis adjusted for demographic, socioeconomic, and clinical variables (HR, 1.50; 95% CI, 1.14-1.96); and in analysis with PPI ever use modeled as a time-varying variable (adjusted HR, 1.35; 95% CI, 1.17-1.55). The association persisted when baseline PPI users were compared directly with H2 receptor antagonist users (adjusted HR, 1.39; 95% CI, 1.01-1.91) and with

propensity score—matched nonusers (HR, 1.76; 95% CI, 1.13-2.74). In the Geisinger Health System replication cohort, PPI use was associated with CKD in all analyses, including a time-varying new-user design (adjusted HR, 1.24; 95% CI, 1.20-1.28). Twice-daily PPI dosing (adjusted HR, 1.46; 95% CI, 1.28-1.67) was associated with a higher risk than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 214.

215. Lazarus' data was confirmed and expanded by Yan Xie, et al.¹² Using Department of Veterans Affairs national databases to build a primary cohort of new users of PPI (n=173,321) and new users of histamine H2-receptor antagonists (H2 blockers; n=20,270), this study patients over 5 years to ascertain renal outcomes. In adjusted Cox survival models, the PPI group, compared with the H2 blockers group, had an increased risk of CKD, doubling of serum creatinine level, and end-stage renal disease.

ANSWER: Abbott admits that a study was published in the Kidney International in 2017 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies any remaining or inconsistent allegations of paragraph 215.

216. However, evidence of the connection of PPIs with AIN and CKD existed as early as 2007, and at no point did any one of the defendants seek to include appropriate warnings of renal dysfunction and/or renal disease in the labels for any of their PPI products.

ANSWER: Abbott denies the allegations of paragraph 216.

217. In Brewster and Perazella's review, they found that not only are PPIs "clearly associated with the development of AIN," most PPI patients they studied were "left with some level of chronic kidney disease." This CKD existed despite recovery of kidney function following PPI withdrawal.

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published literature and states that the publication speaks for itself. Abbott denies the remaining allegations of paragraph 217.

218. Furthermore, Harmark, et al., noted that the Netherlands Pharmacovigilance Centre Lareb received reports of AIN with the use of omeprazole, pantoprazole, and rabeprazole, demonstrating that "AIN is a complication associated with all PPIs."

ANSWER: Abbott admits that the publication referenced in this paragraph is in the published

literature and states that the publication speaks for itself. Abbott denies the remaining allegations of paragraph 218.

219. In spite of their commercial success and global popularity, up to 70% of PPIs may be used inappropriately for indications or durations that were never tested or approved, despite the fact that studies have shown both a dose response relationship and greater hazard with longer periods of use. See Xie (2016) and Lazarus (2016) cited above.

ANSWER: Abbott denies the allegations of paragraph 219.

220. As a result of the defective nature of PPIs, even if used as directed by a physician or healthcare professional, persons who ingested PPIs have been exposed to significant risks stemming from unindicated and/or long-term usage.

ANSWER: Abbott denies the allegations of paragraph 220.

221. From these findings, PPIs and/or their metabolites — substances formed via metabolism — have been found to deposit within the spaces between the tubules of the kidney and act in such a way to mediate acute interstitial nephritis ("AIN"), a sudden kidney inflammation that can result in mild to severe problems.

ANSWER: Abbott denies that the mechanism by which drugs may cause AIN has been established. Takeda further denies any remaining or inconsistent allegations of paragraph 221.

222. PPI-induced AIN is difficult to diagnose with less than half of patients reporting a fever and, instead, most commonly complaining of non-specific symptoms such as fatigue, nausea, and weakness.

ANSWER: Abbott admits that not every patient diagnosed with AIN presents with a fever. Abbott denies any remaining or inconsistent allegations of paragraph 222.

223. In April 2016, a study published in the *Journal of Nephrology* suggested that the development of and failure to treat AIN could lead to chronic kidney disease and end-stage renal disease, which requires dialysis or kidney transplant to manage.

ANSWER: Abbott admits that a study was published in the *Journal of Nephrology* in April 2016 which referenced use of PPI products. Abbott states that this study speaks for itself. Abbott denies that Prevacid® causes chronic kidney disease or end stage renal failure, and further denies any remaining or inconsistent allegations of paragraph 223.

224. CKD describes a slow and progressive decline in kidney function that is manifested

by fibrotic changes that occur in the functional unit of the kidney, known as the “nephron”. Such fibrotic changes can be accompanied by atrophy and loss of nephrons, which as it progresses can result in ESRD. As the kidneys lose their ability to function properly, waste products that normally are filtered from the blood by the kidney can build to dangerously high levels resulting in numerous, serious complications ranging from nerve damage and heart disease to kidney failure and death.

ANSWER: Abbott denies the allegations characterizing chronic kidney disease in paragraph 224 and further denies that Prevacid® causes chronic kidney disease or end stage renal failure.

225. Prompt diagnosis and rapid withdrawal of the offending agent are key in order to preserve kidney function. While AIN can typically be treated early in the course of disease, once it has progressed to CKD it is incurable and can only be managed, which, combined with the lack of numerous early-onset symptoms, highlights the need for screening of at-risk individuals. In failing to warn physicians and consumers of this clear connection, the defendants, and each of them, prevented physicians from making informed choices to stop the offending drug, in this case the Nexium (esomeprazole) product ingested by the plaintiff herein.

ANSWER: Abbott states that AIN is typically reversible on removal of offending agent, though recovery of kidney function is in some cases incomplete. Abbott further denies the remaining allegations of paragraph 225.

226. Consumers, including the Plaintiff, who have used PPIs for the treatment of increased gastric acid have and had several alternative safer products available to treat the conditions and have not been adequately warned about the significant risks and lack of benefits associated with PPI therapy.

ANSWER: Abbott denies the allegations of paragraph 226.

227. Upon information and belief, this failure to warn was a deliberate effort by the defendants, individually and collectively, to continue to reap profits from its blockbuster PPI products from at least 1989 when Prilosec was first approved up through the present day.

ANSWER: Abbott denies the allegations of paragraph 227.

228. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his [sic] physicians the true and significant risks associated with PPI use through the following acts or omissions:

ANSWER: Abbott denies the allegations of paragraph 228.

229. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite also having evidence from its non-clinical studies that the kidneys of exposed test animals showed pathological changes

consistent with acute and chronic kidney disease during the early phase testing, and instead determined that the laboratory animals (rats, mice, dogs, rabbits) were suffering from some species-inherent form of chronic kidney disease (“chronic progressive nephropathy” or “CPN”) rather than a PPI-induced kidney disease.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 229, and therefore denies them.

230. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite also having evidence from its non-clinical studies that the kidneys of exposed test animals showed pathological changes consistent with acute and chronic kidney disease during the early phase testing, and instead determined that the laboratory animals (rats, mice, dogs, rabbits) were suffering from some species-inherent form of chronic kidney disease (“chronic progressive nephropathy” or “CPN”) rather than a PPI-induced kidney disease.

ANSWER: Abbott denies the allegations of paragraph 230.

231. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite clinical evidence from published studies beginning as early as 1992 and continuing up through the early and mid 2000s that PPIs as a class were implicated in cases of acute kidney injury, including chronic kidney disease. This despite the fact that over the many years of its sale and distribution of its PPIs recommendations were made by researchers published in the peer reviewed scientific literature that further testing and elucidation of mechanism be performed by the pharmaceutical industry.

ANSWER: Abbott denies the allegations of paragraph 231.

232. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite clinical evidence from published studies beginning as early as 1992 and continuing up through the early and mid 2000s that PPIs as a class were implicated in cases of acute kidney injury, including chronic kidney disease. This despite the fact that over the many years of its sale and distribution of its PPIs recommendations were made by researchers published in the peer reviewed scientific literature that further testing and elucidation of mechanism be performed by the pharmaceutical industry.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph

232, and therefore denies them.

233. Upon Information and belief, Defendant Abbott never conducted a study specifically designed to test the renal safety of its product despite increasing reports of adverse renal events, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease. Upon information and belief, Abbott affirmatively downplayed and/or underreported adverse renal events in an effort to hide kidney disease and its consequences from regulatory authorities, and the prescribers and consumers of PPI products.

ANSWER: Abbott denies the allegations of paragraph 233.

234. Upon Information and belief, the Takeda Defendants never conducted a study specifically designed to test the renal safety of its product despite increasing reports of adverse renal events, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 234, and therefore denies them.

235. Upon information and belief, the Takeda Defendants affirmatively downplayed and/or underreported adverse renal events in an effort to hide kidney disease and its consequences from regulatory authorities, and the prescribers and consumers of PPI products.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 235, and therefore denies them.

236. Upon information and belief, Abbott, did not conduct renal safety testing of its product, despite signals observed in the non-clinical experimental studies, signals emerging from the published literature and from adverse event reports both from clinical trials and spontaneous reporting from the community, because Abbott knew that such testing would reveal renal abnormalities, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

ANSWER: Abbott denies the allegations of paragraph 236.

237. Upon information and belief, the Takeda Defendants, did not conduct renal safety testing of its product, despite signals observed in the non-clinical experimental studies, signals emerging from the published literature and from adverse event reports both from clinical trials and spontaneous reporting from the community, because the Takeda Defendants knew that such testing would reveal renal abnormalities, including events of renal failure, both acute and chronic, acute interstitial nephritis, which defendants knew can progress to chronic interstitial nephritis, fibrosis, loss of nephrons, and ultimately chronic kidney disease and/or end stage renal disease.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 237, and therefore denies them.

238. Upon information and belief the failure and omissions of Abbott and Takeda, individually and collectively, to conduct appropriate renal safety testing of its lansoprazole and dexlansoprazole PPIs was a deliberate and knowing effort by these defendants individually and collectively to hide renal safety issues from the regulatory authorities, prescribing physicians and the consuming public.

ANSWER: Abbott denies the allegations of paragraph 238.

239. Upon information and belief, the failure and omissions of the Takeda Defendants and Abbott, individually and collectively, to conduct appropriate renal safety testing of its lansoprazole and dexlansoprazole PPIs was committed as part of a deliberate and conscious series of acts, and/or a conspiracy or scheme to reap continued profits from its blockbuster PPI products without disclosing renal safety issues all at the expense of human health, welfare and safety.

ANSWER: Abbott denies the allegations of paragraph 239.

240. All Defendants, individually and collectively, concealed and continue to conceal their knowledge that PPIs can cause kidney injuries from Plaintiff, other consumers, and the medical community. Specifically, Defendants have failed to adequately inform consumers and the prescribing medical community against the serious risks associated with PPIs and have completely failed to warn against the risk of CKD, ESRD, AKI or Renal Failure.

ANSWER: Abbott denies the allegations of paragraph 240.

241. All Defendants, individually and collectively, concealed and continue to conceal their knowledge that PPI users should undergo routine laboratory testing to monitor renal function and should discontinue PPI use at the first sign of abnormal findings. Defendants never warned the medical community in the United States that renal function should be monitored and that PPIs should be discontinued immediately at the first sign of an abnormality and still do not warn of this

ANSWER: Abbott denies the allegations of paragraph 241.

242. All Defendants, individually and collectively, concealed this knowledge despite the fact that they knew that immediate removal of the offending drug was critical as the first line treatment of a drug induced nephrotoxicity or renal injury and that this swift action was necessary to avoid long term, chronic and irreversible kidney damage.

ANSWER: Abbott denies the allegations of paragraph 242.

243. Furthermore, all Defendants, individually and collectively, concealed this knowledge from the medical community in the United States despite warning physicians in Japan and elsewhere, as early as the 1990's, of the risk of interstitial nephritis, renal failure, and the need for vigilant monitoring of renal function via laboratory measurements.

ANSWER: Abbott denies the allegations of paragraph 243.

244. All Defendants, individually and collectively, fraudulently and intentionally hired key opinion leaders to downplay the risks of PPIs, including the risk of serious and permanent kidney injury.

ANSWER: Abbott denies the allegations of paragraph 244.

245. To this day, Defendants, individually and collectively, still do not warn US based physicians that they should be vigilantly monitoring renal function while patients are taking PPIs for signs of kidney injury including acute or chronic renal failure, acute or chronic interstitial nephritis or acute and/or chronic kidney injury.

ANSWER: Abbott states that the allegations of paragraph 245 are premised on legal conclusions to which no response is required. If a response is required, Abbott admits that the FDA-approved product labeling speaks for itself. Abbott denies any remaining or inconsistent allegations.

246. To this day, Defendants, individually and collectively, deny that the use of PPIs poses a risk of chronic kidney disease.

ANSWER: Abbott denies that Prevacid® poses a risk of kidney disease and denies the allegations of paragraph 246.

247. To this day, Defendants, individually and collectively, deny that PPIs are a nephrotoxic medication.

ANSWER: Abbott denies that Prevacid® is or was “nephrotoxic” and denies the allegations of paragraph 247.

248. To this day, Defendants, individually and collectively, fraudulently conceal the risks that PPIs pose to the kidney.

ANSWER: Abbott denies the allegations of paragraph 248.

249. To this day, Defendants, individually and collectively, deny that PPI users should be have their renal function monitored for signs of renal injury.

ANSWER: Abbott denies that Prevacid® causes renal injuries and denies the remaining allegations of paragraph 249.

250. As a result of Defendants' actions and inactions, Plaintiff was injured due to her ingestion of PPIs, which caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

ANSWER: Abbott denies the allegations of paragraph 250.

251. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

ANSWER: Abbott denies the allegations of paragraph 251.

252. As a direct result of ingesting PPIs, Plaintiff has been permanently and severely injured, having suffered serious consequences from PPI use. Plaintiff requires and will in the future require ongoing medical care and treatment.

ANSWER: Abbott denies the allegations of paragraph 252.

253. Plaintiff, as a direct and proximate result of PPI use, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses, and living related expenses due to her new lifestyle.

ANSWER: Abbott denies the allegations of paragraph 253.

254. Plaintiff would not have used PPIs had Defendants properly disclosed the risks associated with long-term use.

ANSWER: Abbott denies the allegations of paragraph 254.

282. Defendants, through their affirmative misrepresentations and/or omissions, actively concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with

the use of Defendants' PPI Products.⁴

ANSWER: Abbott denies the allegations of paragraph 282.

283. Defendants concealed and continue to conceal from Plaintiff, other consumers and/or the medical community that Defendants' PPI Products can cause kidney injuries. Specifically, Defendants failed to adequately inform Plaintiff, other consumers and/or the medical community about the serious risks associated with Defendants' PPI Products, and Defendants completely failed to warn against the risk of AKI, CKD and ESRD, and Defendants still fail to warn of these risks, even to this day. Defendants have concealed and continue to conceal and have failed to adequately inform Plaintiff, other consumers, Plaintiff's physicians and/or others within the medical community that over-the-counter PPI Products are associated with AIN, and fail to warn and inform regarding the risk of AIN developing into CKD and ESRD.

ANSWER: Abbott denies the allegations of paragraph 283.

284. Defendants concealed and continue to conceal that Defendants' PPI Products can cause consumers to become physically dependent on PPI treatment. Specifically, Defendants have failed to inform consumers and/or healthcare providers that a patient's symptoms may worsen after the withdrawal of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 284.

285. As a result of Defendants' actions, Plaintiff and/or Plaintiff healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this Master Long Form Complaint, and that those risks were the direct and proximate result of Defendants' acts, omissions and misrepresentations.

ANSWER: Abbott denies the allegations of paragraph 285.

286. Plaintiff would not have used Defendants' PPI Products had Defendants properly disclosed the risks associated with long-term use.

ANSWER: Abbott denies the allegations of paragraph 286.

287. Defendants had an obligation to comply with the law in the manufacture, design and sale of Defendants' respective PPI Products.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no answer is required. To the extent that these allegations are construed

⁴ Plaintiff's Complaint omits paragraphs 255 through 281.

as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 287.

288. Materials, including advertisements, press releases, website publications and other communications regarding Defendants' PPI Products, are part of the labeling of the Defendants' respective PPI Products, and Defendants could have altered the same without FDA approval.

ANSWER: Abbott states that the allegations of paragraph 288 constitute legal conclusions to which no answer is required. To the extent that the allegations are construed as factual allegations directed to Abbott, they are denied.

289. Defendants' marketing campaigns willfully and intentionally misrepresented the risks of PPI Products and failed to warn about the risks of acute interstitial nephritis, acute kidney failure, chronic kidney disease and other kidney injuries.

ANSWER: To the extent that the allegations of paragraph 289 are directed to Abbott, Abbott denies them.

290. Defendants engaged in off-label promotion of their respective PPI Products for indications that were not approved, including, but not limited to, long-term ingestion of PPI Products for a duration for which the products were not originally approved.

ANSWER: To the extent that the allegations of paragraph 290 are directed to Abbott, Abbott denies them.

291. Defendants' marketing campaigns and advertising to consumers failed to adequately instruct consumers regarding the appropriate duration for using their respective over-the-counter PPI Products.

ANSWER: To the extent that the allegations of paragraph 291 are directed to Abbott, Abbott denies them.

292. Defendants knew or should have known of the risks of AIN, AKI, CKD and ESRD based on the data available to them or that could have been generated by them, including, but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, preclinical studies, clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post-marketing reports and regulatory authority investigations.

ANSWER: Abbott denies the allegations of paragraph 292.

293. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AIN.

ANSWER: To the extent that the allegations of paragraph 293 are directed to Abbott, Abbott denies them.

294. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of AKI.

ANSWER: To the extent that the allegations of paragraph 294 are directed to Abbott, Abbott denies them.

295. To date Defendants have failed to submit proposed labeling for their respective PPI Products to the FDA regarding the risks of CKD.

ANSWER: To the extent that the allegations of paragraph 295 are directed to Abbott, Abbott denies them.

296. At all times, Defendants could have implemented changes to the labeling of their respective PPI Products regarding the risks of AIN, AKI, CKD and ESRD.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies that it had the authority to revise or modify the FDA-approved labeling for Prevacid®, and denies the remaining allegations of paragraph 296.

297. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq.

ANSWER: Abbott states that the allegations of paragraph 297 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, they are denied.

298. With respect to Defendants' PPI Products, Defendants have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

- a. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading;
- b. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because words, statements or other information required by or under authority of chapter 21

- U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- c. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because their labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users;
 - d. Defendants' PPI Products are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof;
 - e. Defendants' PPI Products do not contain adequate directions for use pursuant to 21 CFR § 201.5, because of, among other reasons, omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application;
 - f. Defendants violated 21 CFR § 201.56 because the labeling of their respective prescription PPI Products were and are not informative and accurate;
 - g. Defendants' prescription PPI Products are misbranded pursuant to 21 CFR § 201.56 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading;
 - h. Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for monitoring of patients who took their respective prescription PPI Products;
 - i. Defendants' prescription PPI products are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established;
 - j. Defendants' over-the-counter PPI Products are mislabeled pursuant to 21 CFR §201.66 because they were and are not informative and accurate;
 - k. Defendants' over-the-counter PPI Products are misbranded pursuant to 21 CFR §201.66 because their labeling was not updated as new information became available that caused the labeling to become inaccurate, false or misleading;
 - l. Defendants' PPI Products violate 21 CFR § 210.1 because the process by which they were manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meet the quality and purity characteristic that they purport or are represented to possess;
 - m. Defendants' PPI Products violate 21 CFR § 210.22 because the labeling and

- packaging materials do not meet the appropriate specifications;
- n. Defendants' PPI Products violate 21 CFR § 211.165 because the test methods Defendants employed are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented;
 - o. Defendants' PPI Products violate 21 CFR § 211.165 in that they fail to meet established standards or specifications and any other relevant quality control criteria;
 - p. Defendants' PPI Products violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the PPI Products were not followed;
 - q. Defendants' PPI Products violate 21 CFR § 310.303 in that they are not safe and effective for their intended use;
 - r. Defendants violated 21 CFR § 310.303 by failing to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA;
 - s. Defendants violated 21 CFR § 310.305 and 314.80 by failing to report adverse events associated with their respective PPI Products as soon as possible or at least within 15 days of the initial receipt of the adverse drug experience report;
 - t. Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with their respective PPI Products, and evaluating the cause of the adverse event;
 - u. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA;
 - v. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences;
 - w. Defendants violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports it submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up";
 - x. Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of Defendant's PPI Products or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor;
 - y. Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for

- example, labeling changes or studies initiated); and
- z. Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.
- aa. Defendants failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff.

ANSWER: Abbott states that the allegations of paragraph 298 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, Abbott denies them, including all subparts.

**ESTOPPEL FROM PLEADING AND TOLLING OF
APPLICABLE STATUTES OF LIMITATIONS**

299. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

300. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert tolling of relevant statutes of limitations, but denies that Plaintiff is entitled to such tolling. Abbott denies any remaining allegations of paragraph 300.

301. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff knew or, through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott admits that Plaintiff purports to assert application of the discovery rule, but denies that Plaintiff is entitled to such application. Abbott denies any remaining allegations of paragraph 301.

302. Despite diligent investigation by the Plaintiff into the cause of their injuries, the nature of the Plaintiff's injuries and damages and their relationship to the PPI Products was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 302 are construed as factual allegations directed to Abbott, Abbott denies them.

303. The running of the statute of limitations in this case is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and/or the consuming public of the true risks associated with the PPI Products. As a result of the Defendants' fraudulent concealment, the Plaintiff and/or Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence, that the Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. If the allegations of paragraph 303 are construed as factual allegations directed to Abbott, Abbott denies them.

304. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of PPI Products. The Defendants were under a duty to disclose the true character, quality and nature of PPI Products because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to the Plaintiff, their medical providers and/or to their health facilities.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute

legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 304.

305. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and/or medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

ANSWER: To the extent that the allegations of paragraph 305 are directed to Abbott, Abbott denies them.

306. Defendants were and continue to be in possession of information and data that shows the risk and dangers of these products that is not otherwise in the possession or available to Plaintiff and/or their healthcare providers.

ANSWER: To the extent that the allegations of paragraph 306 are directed to Abbott, Abbott denies them.

307. At the time of the Plaintiff's injuries, Plaintiff and/or the Plaintiff's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because the Plaintiff and the Plaintiff's healthcare providers reasonably relied on Defendants' representations that PPI Products do not cause kidney injury and/or death.

ANSWER: To the extent that the allegations of paragraph 307 are directed to Abbott, Abbott denies them.

308. At no time prior to the Plaintiff's eventual discovery of wrongdoing did any of Plaintiff's doctors ever inform, advise, suggest or otherwise imply that the Plaintiff's PPI Product use was a potential contributing cause of the Plaintiff's kidney injuries.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products and medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 308.

309. Plaintiff reasonably relied on the skill and judgment of the Plaintiff's doctors and had no reason to further investigate, inquire into or suspect that PPI Products caused the Plaintiff's

conditions.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products or medical conditions, and therefore denies them. Abbott denies any remaining allegations of paragraph 309.

310. Plaintiff exercised reasonable diligence in an attempt to discover the cause of their kidney injuries. Plaintiff relied on their physicians to advise them of any known complications. Plaintiff had no reason to believe their injuries were the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's medical condition, and therefore denies them. Abbott denies any remaining allegations of paragraph 310.

311. The Plaintiff had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, the Plaintiff could not have reasonably discovered the wrongdoing at the time of her injury.

ANSWER: To the extent the allegations of paragraph 311 are directed to Abbott, Abbott denies them.

312. At the time of Plaintiff's injuries, Plaintiff did not have access to or actually receive any studies or information recognizing the increased risk of kidney injuries with PPI Product use or have any discussions with their doctors that there was an association between their kidney injuries and PPI Product use.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI products or medical condition, and therefore denies them. Abbott denies any remaining allegations of paragraph 312.

CAUSES OF ACTION

COUNT I

STRICT PRODUCT LIABILITY

313. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

314. At the time of Plaintiff's injuries, the PPI Products manufactured by the Defendants were defective and unreasonably dangerous to foreseeable consumers, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 314 and specifically denies that it manufactured Prevacid® and denies that Prevacid® was defective or unreasonably dangerous.

315. At the time of Plaintiff's injuries, Defendants placed PPI Products into the stream of commerce that were defective and in an unreasonably dangerous condition to foreseeable users, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 315 and specifically denies that Prevacid® was defective or unreasonably dangerous.

316. At all times herein mentioned, Defendants have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed PPI Products as described herein that were used by the Plaintiff.

ANSWER: Abbott admits that at various times in the past, it researched, tested, packaged, marketed, and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 316, and specifically denies that it manufactured Prevacid®.

317. Defendants' PPI Products were expected to and did reach consumers, handlers and persons coming into contact with said products without substantial change in the condition in

which they were produced, manufactured, sold, distributed and marketed by the Defendants.

ANSWER: Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® “did reach” users without substantial change in the condition in which it was distributed, and therefore denies them. Abbott denies the remaining allegations of paragraph 317.

318. Defendants’ PPI Products were manufactured in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiff.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff’s use of Prevacid®, and therefore denies them. Abbott denies the remaining allegations of paragraph 318, and specifically denies that it manufactured Prevacid®.

319. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 319, and denies that Prevacid® is or was defective and specifically denies that it manufactured Prevacid®.

320. At all times herein mentioned, the PPI Products were in a defective condition and unsafe, and Defendants knew or had reason to know that their PPI Products were defective and unsafe, including when used in the formulation and manner recommended by the Defendants.

ANSWER: Abbott denies the allegations of paragraph 320, and specifically denies that Prevacid® is or was defective or unsafe.

321. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants, manufacturers and/or suppliers, the PPI Products were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect, and more dangerous than other medications on the market designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory

drug-induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 321, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

322. Defendants knew or should have known that at all times herein mentioned their PPI Products were in a defective condition and were and are inherently dangerous and unsafe.

ANSWER: Abbott denies the allegations of paragraph 322, and specifically denies that Prevacid® is or was defective, inherently dangerous, or unsafe.

323. At the time Plaintiff used Defendants' PPI Products, the PPI Products were being used for the purposes and in a manner normally intended and foreseeable, namely to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 323, and therefore denies them.

324. Defendants, with this knowledge, voluntarily designed their PPI Products in a dangerous condition for use by the public and the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 324.

325. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended and foreseeable use.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining or inconsistent allegations of paragraph 325.

326. Defendants created a product unreasonably dangerous for its intended and foreseeable use.

ANSWER: Abbott denies the allegations of paragraph 326.

327. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that PPI Products left the hands of Defendants in a defective condition and were unreasonably

dangerous to its intended users.

ANSWER: Abbott denies the allegations of paragraph 327, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

328. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which they were manufactured.

ANSWER: Abbott denies the allegations of paragraph 328, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

329. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers, and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 329.

330. Plaintiff could not, by the exercise of reasonable care, have discovered the PPI Products' defects herein mentioned and perceived their danger.

ANSWER: Abbott denies the allegations of paragraph 330, and specifically denies that Prevacid® is or was defective or dangerous.

331. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including kidney injuries and other severe and personal injuries which are permanent and lasting in nature, and the Defendants failed to adequately warn of said risk.

ANSWER: Abbott denies the allegations of paragraph 331.

332. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products created a risk of serious and dangerous side effects, including rebound acid hypersecretion, and the Defendants failed to adequately warn of said risk.

ANSWER: Abbott denies the allegations of paragraph 332, and specifically denies that Prevacid® is or was defective or dangerous.

333. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the PPI Products were ineffective for their intended use of treating peptic disorders, including GERD, peptic ulcer disease, and non-steroidal anti-inflammatory drug induced gastropathy, and that there were less dangerous alternatives on the market to treat peptic disorders.

ANSWER: Abbott denies the allegations of paragraph 333, and specifically denies that Prevacid® is or was defective or dangerous.

334. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

ANSWER: Abbott denies the allegations of paragraph 334, and specifically denies that Prevacid® is or was defective or dangerous.

335. The PPI Products designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate postmarketing surveillance and/or warnings because, even after Defendants knew or should have known of the risks and severe and permanent health consequences from ingesting PPI Products, they failed to provide adequate warnings to users or consumers of the products, and continued to improperly advertise, market and/or promote their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 335, and specifically denies that Prevacid® is or was defective.

336. The PPI Products ingested by the Plaintiff were in the same or substantially similar condition as they were when they left the possession of Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 336, and therefore denies them.

337. Plaintiff did not misuse or materially alter the PPI Products.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 337, and therefore denies them.

338. Defendants are strictly liable for Plaintiff' [sic] injuries in the following ways:

- a. The PPI Products as designed, manufactured, sold and supplied by the Defendants, were defectively designed and placed into the stream of commerce by Defendants

- in a defective and unreasonably dangerous condition;
- b. Defendants failed to properly market, design, manufacture, distribute, supply and sell their PPI Products;
- c. Defendants failed to warn and place adequate warnings and instructions on their PPI Products;
- d. Defendants failed to adequately test their PPI Products;
- e. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the use of PPI Products; and
- f. Feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating the Plaintiff's conditions, while decreasing the risk of kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 338, including all subparts, and specifically denies that Prevacid® is or was defective or dangerous.

339. By reason of the foregoing, Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective PPI Products.

ANSWER: Abbott denies the allegations of paragraph 339.

340. Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Abbott denies the allegations of paragraph 340.

341. These defects in Defendants' PPI Products were a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 341.

342. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 342.

343. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 343.

COUNT II
STRICT PRODUCT LIABILITY – DESIGN DEFECT

344. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

345. At all times relevant, Defendants' PPI Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce.

ANSWER: Abbott denies the allegations of paragraph 345, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

346. Defendants' PPI Products were defective in design or formulation in that they were not merchantable, reasonably suitable and/or safe for their intended and foreseeable use, and their condition when sold was the proximate cause and/or a substantial factor of the injuries sustained by Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 346.

347. Defendants' PPI Products did not perform safely or as Plaintiff or an ordinary consumer would have expected.

ANSWER: Abbott denies the allegations of paragraph 347.

348. At all times relevant, the PPI Products were used as intended or in a way reasonably foreseeable to the Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 348, and therefore denies them.

349. Defendants placed their PPI Products into the stream of commerce with wanton and reckless disregard for public safety.

ANSWER: Abbott denies the allegations of paragraph 349.

350. At all times relevant, Defendants' PPI Products were expected to reach, and did

reach, Plaintiff, without substantial change in the condition in which they were sold.

ANSWER: Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® “did reach” intended consumers, including Plaintiff, without substantial change in the condition in which it was distributed, and therefore denies them. Abbott specifically denies that it was a manufacturer of Prevacid®, and further denies any remaining allegations of paragraph 350.

351. The PPI Products were sold in an unsafe, defective and inherently dangerous Condition.

ANSWER: Abbott denies the allegations of paragraph 351.

352. The PPI Products contained defects in their design which render the drugs dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants. The design defects render the PPI Products more dangerous than other drugs designed to treat peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy, and cause an unreasonable increased risk of injury, including but not limited to life-threatening kidney injuries.

ANSWER: Abbott denies the allegations of paragraph 352, and specifically denies that Prevacid® is or was defective or dangerous.

353. The PPI Products were in a defective condition and unsafe, and Defendants knew, had reason to know or should have known that the PPI Products were defective and unsafe, even when used as instructed.

ANSWER: Abbott denies the allegations of paragraph 353, and specifically denies that Prevacid® is or was defective or unsafe.

354. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of serious kidney injuries that may be irreversible, permanently disabling and life-threatening, is high in light of the intended and reasonably foreseeable use of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 354.

355. The risks of harm associated with the design of Defendants’ PPI Products are higher

than necessary.

ANSWER: Abbott denies the allegations of paragraph 355.

356. It is unlikely that users would be aware of the risks associated with Defendants' PPI Products, and the Plaintiff specifically was not aware of these risks, nor would she expect such risks.

ANSWER: Abbott denies the allegations of paragraph 356.

357. The PPI Products manufactured and supplied by Defendants were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of PPI Products, exceeded the benefits associated with the design or formulation of the PPI Products, or they were more dangerous than an ordinary consumer would expect.

ANSWER: Abbott denies the allegations of paragraph 357.

358. As set forth elsewhere in this Complaint, the foreseeable risks of the PPI Products, include but are not limited to the following:

- a. the nature and magnitude of risks associated with the product design in light of the intended and reasonably foreseeable uses;
- b. the unlikely awareness to the users of PPI Products of this risk due to its inadequate warnings and Defendants' inappropriate and misleading promotion of the benefits of PPI Products, among other reasons;
- c. the high likelihood that the faulty design or formulation would cause harm to its users in light of the intended and reasonably foreseeable use as PPI Products, among other reasons;
- d. the design or formulation of PPI Products produced or manufactured by Defendants failed to conform to applicable public or private product standards in effect when it left the control of the manufacturer since there were available, more effective feasible alternative designs, including but not limited to those used of H2 Blockers and other available treatments, existed that were capable of treating Plaintiff's conditions, while not as prone to cause injury specifically, the risk of kidney injuries.
- e. the design or formulation of PPI Products produced or manufactured by Defendants is more dangerous than the reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner in that the risks of injury, as defined above, are more dangerous than one would expect when using PPI Products.

ANSWER: Abbott denies the allegations of paragraph 358, including all subparts.

359. The design of Defendants' PPI Products did not conform to any applicable public or private product standard that was in effect when the PPI Products left the Defendants' control.

ANSWER: Abbott denies the allegations of paragraph 359.

360. The PPI Products' designs are more dangerous than a reasonably prudent consumer would expect when used in their intended or reasonably foreseeable manner. The PPI Products are more dangerous than Plaintiff expected.

ANSWER: Abbott denies the allegations of paragraph 360.

361. The intended or actual utility of PPI Products is not of such benefit to justify the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott denies the allegations of paragraph 361.

362. At the time the PPI Products left Defendants' control, it was both technically and economically feasible to have an alternative design that would not have caused kidney injuries that may be irreversible, permanently disabling and life-threatening, or an alternative design that would have substantially reduced the risk of these injuries.

ANSWER: Abbott denies the allegations of paragraph 362.

363. It was both technically and economically feasible to provide a safer alternative product that would have prevented the harm suffered by Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 363.

364. Defendants' conduct was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from Plaintiff, the medical community and the general public. Defendants made conscious decisions not to warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 364.

365. The unreasonably dangerous nature of Defendants' PPI Products caused serious harm to Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 365 and specifically denies that Prevacid® is or was unreasonably dangerous.

366. Defendants' PPI Products are defective in their design which renders the PPI Products dangerous to consumers, including Plaintiff, when used as intended or as reasonably foreseeable to Defendants.

ANSWER: Abbott denies the allegations of paragraph 366 and specifically denies that Prevacid® is or was dangerous.

367. The design defects render the PPI Products more dangerous than other products used for the same intended purpose, and cause an unreasonable increased risk of harm.

ANSWER: Abbott denies the allegations of paragraph 367 and specifically denies that Prevacid® is or was dangerous.

368. The PPI Products' design is defective and unsafe, and Defendants knew or had reason to know that the PPI Products were defective and unsafe in their design when used as instructed and in a foreseeable manner for the treatment of peptic disorders by consumers, including the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 368 and specifically denies that Prevacid® is or was defective or unsafe.

369. The nature and magnitude of the risk of harm associated with the design of the PPI Products, including the risk of kidney injury that may lead to permanently disabling and life threatening or life-ending conditions, was high in light of the intended and reasonably foreseeable use of PPI Products by patients for treatment of peptic disorders.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 369.

370. Users of PPI Products would not be aware of the risks of kidney injuries associated with either the defective design or warnings associated with PPI Products through warnings, general knowledge or otherwise, and Plaintiff was specifically unaware of these risks, and would not be expected to be aware of these risks.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 370.

371. The intended or actual utility and benefit of the PPI Products does not justify the risk of kidney injuries that may be irreversible, permanently disabling, life-threatening or life-ending.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 371.

372. The design of the PPI Products was negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Abbott denies the allegations of paragraph 372.

373. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of kidney injury.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 373.

374. The warnings and instructions for use accompanying the PPI Products were negligently formulated by the Defendants in disregard of the known risk of rebound acid hypersecretion.

ANSWER: Abbott denies the allegations of paragraph 374.

375. The defects in design and warnings caused and/or increased the risk of harm of Plaintiff [sic] injuries and damages.

ANSWER: Abbott denies the allegations of paragraph 375.

376. The Defendants failed to provide an adequate warning as to the risks of PPI Products and for this reason Defendants may not claim that PPI Products are not defective in design or formulation, though it is unsafe.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 376 and specifically denies that Prevacid® is defective in design or formulation, or unsafe.

377. As a direct and proximate result of Plaintiff's use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

ANSWER: Abbott denies the allegations of paragraph 377.

378. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages.

ANSWER: Abbott denies the allegations of paragraph 378.

379. Additionally, as a direct and proximate result of the foregoing, Defendants' defective design, manufacturing defect and inadequate warnings on the PPI Products were acts that amount to willful, wanton and/or reckless conduct by Defendants.

ANSWER: Abbott denies the allegations of paragraph 379.

380. The defective nature of the PPI Products was a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 380 and specifically denies that Prevacid® is or was defective.

381. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 381.

382. Defendants' conduct, as described herein, was extreme and outrageous.

ANSWER: Abbott denies the allegations of paragraph 382.

383. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 383.

COUNT III
STRICT PRODUCT LIABILITY – FAILURE TO WARN

384. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States [*sic*].

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

385. Defendants manufactured, distributed and/or sold the PPI Products that were dangerous and presented a high risk of serious kidney and related personal injuries when used as intended or in foreseeable way, notwithstanding the Defendants' knowledge of an increased risk of such injuries, they failed to adequately warn consumers and/or their health care providers of such risks.

ANSWER: Abbott denies the allegations of paragraph 385, specifically denies that

Prevacid® is or was dangerous or causes kidney or other personal injuries, and further specifically denies that it manufactured Prevacid®.

386. In addition to, or in the alternative, the PPI Products manufactured and supplied by Defendants were defective due to inadequate post-marketing warning or instructions since, after Defendants knew or should have known of the risk of serious bodily harm as a result of PPI Products, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the product, knowing the product could cause serious injury.

ANSWER: Abbott denies the allegations of paragraph 386 and specifically denies that Prevacid® is or was defective.

387. Defendants had a duty to warn Plaintiff and their healthcare providers regarding the risks associated with ingesting PPI Products and failed to warn of the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 387.

388. Defendants knew, or in the exercise of reasonable care should have known, about the risk of kidney injuries that may be irreversible, permanently disabling and life-threatening that are associated with use of their PPI Products.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 388.

389. Defendants failed to provide adequate warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risk of kidney injury that may be irreversible, permanently disabling and life-threatening in light of the likelihood that the PPI Products would cause these injuries.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further specifically denies that it manufactured Prevacid® and further denies the remaining allegations of paragraph 389.

390. The risks of PPI Products were not open and obvious.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies the allegations of paragraph 390.

391. Defendants failed to update warnings based on information received from surveillance and research conducted after their PPI Products were first approved by the FDA and marketed, sold and used in the United States and throughout the world.

ANSWER: Abbott denies the allegations of paragraph 391.

392. A manufacturer exercising reasonable care would have updated its warnings on the basis of reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Abbott denies the allegations of paragraph 392 and specifically denies that it is or was a manufacturer of Prevacid®.

393. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of kidney injury that may be irreversible, permanently disabling and life-threatening.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, denies that Prevacid® is or was defective or unreasonably dangerous, and further denies the remaining allegations of paragraph 393.

394. When it left Defendants' control, the PPI Products were defective and unreasonably dangerous for failing to warn of the risk of rebound acid hypersecretion that would assist healthcare providers and/or patients who suffer from this after ceasing use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 394, and specifically denies Prevacid® is or was defective or unreasonably dangerous.

395. Plaintiff used the PPI Products for their approved purpose and in a manner normally intended and reasonably foreseeable by the Defendants.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 395, and therefore denies them.

396. Plaintiff and/or Plaintiff's healthcare providers could not, by the exercise of reasonable care, have discovered the defects or perceived the danger of PPI Products because the

risks were not open or obvious.

ANSWER: Abbott denies the allegations of paragraph 396, and specifically denies that Prevacid® is or was defective or unreasonably dangerous.

397. Defendants, as the manufacturers and distributors of the PPI Products, are held to the level of knowledge of an expert in the field.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 397, and specifically denies that it is or was a manufacturer of Prevacid®.

398. The warnings that were given by Defendants were not accurate or clear, and were false and ambiguous.

ANSWER: Abbott denies the allegations of paragraph 398.

399. The warnings that were given by the Defendants failed to properly warn Plaintiff and/or Plaintiff's [sic] healthcare providers of the risks associated with the PPI Products, subjecting Plaintiff to risks that exceeded the benefits to the Plaintiff. Plaintiff, individually and/or Plaintiff through their healthcare providers, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

ANSWER: Abbott denies the allegations of paragraph 399.

400. Defendants had a continuing duty to warn Plaintiff and/or Plaintiff's healthcare providers of the dangers associated with their PPI Products.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 400.

401. Had Plaintiff and/or Plaintiff's healthcare providers received adequate warnings regarding the risks associated with the use of PPI Products, they would not have used them or they would have altered the frequency or duration of use.

ANSWER: Abbott denies the allegations of paragraph 401.

402. Defendants failed to update warnings based on information received after the PPI Products entered the market, and continued to market, promote, detail, distribute and sell PPI Products without appropriately updated and amended warnings.

ANSWER: Abbott denies the allegations of paragraph 402.

403. A manufacturer exercising reasonable and prudent care would have updated warnings on the PPI Products on the basis of epidemiology studies and/or reports of injuries to individuals using PPI Products after FDA approval.

ANSWER: Abbott denies the allegations of paragraph 403.

404. Plaintiff and Plaintiff's healthcare providers were led to believe, through Defendants' use of aggressive and pervasive marketing, promotion and detailing, that Defendants' PPI Products were safe and effective for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 404.

405. The warnings and instructions that were given by Defendants to healthcare providers were not accurate or clear, and were, in fact, false and misleading.

ANSWER: Abbott denies the allegations of paragraph 405.

406. The warnings that were given by the Defendants failed to properly warn physicians and/or other healthcare providers, including those of the Plaintiff, of the risks associated with Defendants' PPI Products, thereby subjecting patients, including the Plaintiff, to unreasonable and foreseeable risks that exceeded the purported and marketed benefits of Defendants' PPI Products.

ANSWER: Abbott denies the allegations of paragraph 406.

407. Plaintiff's healthcare providers reasonably relied upon the representations, warning and instructions provided by Defendants for use and administration of their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 407.

408. Had the Plaintiff and/or their healthcare providers received adequate, appropriate and correct warnings regarding the risks associated with the use of Defendants' PPI Products, these healthcare providers would not have prescribed, recommended, continued to prescribe or continued the recommendation of the PPI Products, or would have altered the duration and frequency of use.

ANSWER: Abbott denies the allegations of paragraph 408.

409. Defendants' conduct as described herein was a substantial factor in causing the Plaintiff's injuries.

ANSWER: Abbott denies the allegations of paragraph 409.

410. As a direct and proximate result of Plaintiff [sic] use of PPI Products as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

ANSWER: Abbott denies the allegations of paragraph 410.

411. As a result of the foregoing acts and omissions, Plaintiff were caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 411.

412. As a direct and proximate result of the foregoing, Plaintiff is entitled to damages. Additionally, Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 412.

COUNT IV **NEGLIGENCE**

413. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

414. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, packaging, selling and/or distributing their PPI Products into the stream of commerce, including a duty to assure that the PPI Products would not

cause users to suffer unreasonable, dangerous side effects.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 414.

415. Defendants failed to exercise ordinary care in the design, research, manufacture, labeling, warnings, marketing, promotion, quality assurance, quality control, sale and/or distribution of their PPI Products in that Defendants knew or should have known that the drugs could proximately cause Plaintiff [sic] injuries and/or presented an unreasonably high risk of injury.

ANSWER: Abbott denies the allegations of paragraph 415.

416. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants and/or employees, acted with carelessness, recklessness, negligence, gross negligence and/or willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying, selling and/or placing into the stream of commerce their PPI Products, including but not limited to the following particular respects:

- a. Failing to use due care in design and/or manufacture of the PPI Products so as to avoid the aforementioned risks to individuals;
- b. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of their PPI Products;
- c. Failing to use reasonable and prudent care so as to conduct sufficient postmarketing pharmacovigilance and pharmacosurveillance;
- d. Failing to recognize the significance of their own and other testing, and information regarding PPI Products, which testing and information evidenced such products are dangerous and potentially harmful to humans;
- e. Failing to respond promptly and appropriately to their own and other testing, and information regarding PPI Products, and failing to promptly and adequately warn of the potential for kidney injuries including acute interstitial nephritis, acute kidney injuries and chronic kidney disease, when using their PPI Products;
- f. Failing to promptly, adequately and appropriately recommend testing and monitoring of patients upon whom PPI Products were used in light of the PPI Products' dangers and potential harm to humans;
- g. Failing to properly, appropriately and adequately monitor the post-market performance of their PPI Products and such products effects on patients;
- h. Aggressively promoting, marketing, advertising and/or selling their PPI Products given their knowledge and experience of their PPI Products' potential harmful effects;
- i. Failing to use reasonable and prudent care in their statements of the efficacy, safety

- and risks of using their PPI Products, which were knowingly false and misleading, in order to influence patients, such as the Plaintiff, to use their PPI Products in excess and/or in preference to safer and effective alternative treatments;
- j. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of kidney injury associated with the use of their PPI Products;
 - k. Failing to accompany their PPI Products with proper and/or accurate warnings regarding all possible adverse side effects and risk of rebound acid hypersecretion associated with the use of their PPI Products;
 - l. Failing to disclose to Plaintiff and/or the medical community their full knowledge and experience regarding the potential dangers and harm associated with use of their PPI Products;
 - m. Failing to disclose to Plaintiff and/or the medical community in an appropriate and timely manner, facts relative to the potential dangers and harm associated with use of their PPI Products;
 - n. Failing to warn Plaintiff and/or Plaintiff's healthcare providers of the severity and duration of such adverse effects;
 - o. Failing to warn Plaintiff and/or Plaintiff's healthcare providers prior to actively encouraging the sale of their PPI Products, either directly or indirectly, orally or in writing, about the increased risk of kidney injury;
 - p. Placing and/or permitting the placement of PPI Products into the stream of commerce without adequate warnings that they are harmful to humans and/or without properly warning of said products' dangerousness;
 - q. Failing to withdraw their PPI Products from the market and stream of commerce, or restrict their use and/or warn of such products' potential dangers, given their knowledge of the dangers and harms associated with use of their PPI Products;
 - r. Failing to respond or react promptly and appropriately to reports of their PPI Products causing harm to patients;
 - s. Disregarding government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of their PPI Products and their potential harm to humans;
 - t. Under-reporting, underestimating and/or downplaying the serious dangers of their PPI Products;
 - u. Failing to exercise reasonable care in informing physicians and healthcare providers using PPI Products about their own knowledge regarding the potential dangers and harm associate with use of their PPI Products;
 - v. Failing to adequately warn Plaintiff and/or Plaintiff's healthcare providers of the known or reasonably foreseeable danger that Plaintiff would suffer serious injuries or death by ingesting Defendants' PPI Products;
 - w. Promoting PPI Products in advertisements, websites and other modes of communication aimed at creating and/or increasing user and consumer demand without regard to the dangers and risks associated using PPI Products;
 - x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries associated with their PPI Products;
 - y. Failing to use due care under the circumstances; and
 - z. Other such acts or omissions constituting negligence and carelessness as may

appear during the course of discovery or at the trial of this matter.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries and further denies the remaining allegations of paragraph 416, including all subparts.

417. Despite the fact that Defendants knew or should have known that the PPI Products caused unreasonable, dangerous risk of kidney injury, Defendants continued to market the PPI Products to consumers, including the medical community and Plaintiff.

ANSWER: Abbott denies that Prevacid® causes kidney injuries, and further denies the remaining allegations of paragraph 417.

418. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described herein, including the failure to comply with federal requirements.

ANSWER: Abbott denies the allegations of paragraph 418.

419. It was foreseeable to Defendants that Defendants' PPI Products, as designed and marketed, would cause serious injury to consumers, including Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 419.

420. Despite the fact that Defendants knew or should have known that their PPI Products caused unreasonable risks of harm when used as intended by the Defendants, the Defendants continued to advertise, market and sell their PPI Products to patients, including the Plaintiff and healthcare providers.

ANSWER: Abbott denies the allegations of paragraph 420.

421. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm (in some cases death), damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ANSWER: Abbott denies the allegations of paragraph 421.

422. Defendants' knowingly and intentionally defectively designed and provided inadequate warnings relating to the design of the PPI Products in willful, wanton and reckless disregard for the safety and well-being of all patients and consumers, including the Plaintiff, for the purpose of achieving profits and market share over safety.

ANSWER: Abbott denies the allegations of paragraph 422.

423. Defendants acted in reckless disregard to public safety and well-being, including

Plaintiff [sic] safety and well-being, and with actual knowledge that the PPI Products were unsafe for their recommended use for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 423.

424. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public, Plaintiff, and/or Plaintiff's healthcare providers concerning the dangers of PPI Products, and consciously decided to aggressively market and sell their PPI Products, putting economic, financial and market share advantage over safety and efficacy considerations.

ANSWER: Abbott denies the allegations of paragraph 424.

425. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 425.

426. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 426.

COUNT V

NEGLIGENCE PER SE

427. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

428. Defendants violated the Federal Food, Drug and Cosmetic Act 21 U.S.C. §301, et seq., and regulations as described herein, including but not limited to 21 U.S.C. §352, 21, CFR § 201.5, 21 CFR § 201.56, 21 CFR § 201.57, 21 CFR § 201.66, 21 CFR § 210.1, 21 CFR § 210.122, 21 CFR § 211.165, 21 CFR § 211.198, 21 CFR § 310.303, 21 CFR §310.305, 21 CFR § 314.80, and 21 CFR § 312.32.

ANSWER: Abbott states that the allegations of paragraph 428 constitute legal conclusions to which no response is required. If these allegations are construed as factual allegations directed to Abbott, Abbott denies them.

429. These statutes and regulations are aimed at preserving the health and safety of Plaintiff and the general public.

ANSWER: Abbott states that the allegations of paragraph 429 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

430. Defendants' acts were the proximate cause and/or a substantial factor in bringing about the harm to the Plaintiff as alleged herein.

ANSWER: Abbott denies the allegations of paragraph 430.

431. Plaintiff is among the class of individuals that these statutes and regulations were designed to protect.

ANSWER: Abbott states that the allegations of paragraph 431 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

432. Plaintiff's injuries are the type that these federal statutes and regulations were intended to prevent.

ANSWER: Abbott states that the allegations of paragraph 432 constitute legal conclusions to which no response is required. To the extent that the allegations of this paragraph are construed as factual allegations directed to Abbott, Abbott denies them.

433. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further

denies the remaining allegations of paragraph 433.

434. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 434.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of this unnumbered "wherefore" paragraph.

COUNT VI **NEGLIGENCE – FAILURE TO TEST**

435. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

436. At all times relevant, Defendants had a duty to Plaintiff to test the PPI Products so that they were reasonably safe for their foreseeable use, including a duty to conduct proper safety studies and to take all reasonable steps necessary to ensure their drugs were not unreasonably dangerous to its consumers and users.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies any remaining allegations of paragraph 436 and specifically denies that Prevacid® was unreasonably dangerous.

437. Defendants did not perform adequate testing on the PPI Products, which were defectively designed, formulated, tested, manufactured, inspected, distributed, marketed, supplied and/or sold to Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 437.

438. Defendants also failed to properly and adequately test the PPI Products to discover their potential for causing deleterious, permanent, and profound injuries to the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 438.

439. Defendants failed to properly and adequately analyze the data resulting from pre-marketing tests of PPI products.

ANSWER: Abbott denies the allegations of paragraph 439.

440. Additionally, Defendants failed to conduct adequate and sufficient post-market testing and surveillance of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 440.

441. Through the formulating of the PPI Products, and before the initiation of the drugs' mass manufacture, Defendants knew or should have known in the exercise of ordinary care that the chemical reactions inherent to PPI Products' mechanism of action would present a health hazard to potential users such as the Plaintiff named herein.

ANSWER: Abbott denies the allegations of paragraph 441.

442. Adequate testing would have revealed the serious injuries, including but not limited to renal injury and/or failure and, in some cases, death caused by the use of the PPI Products.

ANSWER: Abbott denies the allegations of paragraph 442.

443. The dangers presented by the PPI Products are so great that reasonable healthcare professionals would not prescribe their use if they knew of the risks.

ANSWER: Abbott denies the allegations of paragraph 443.

444. Defendants knew or reasonably should have known that Plaintiff would foreseeably suffer economic damages and/or injuries and/or be at an increased risk of suffering damages and injuries as a result of their failure to exercise ordinary care in the design of the PPI Products by failing to conduct appropriate testing.

ANSWER: Abbott denies the allegations of paragraph 444.

445. Defendants are strictly liable for Plaintiff's injuries resulting from the Defendants'

failure to test their PPI Products.

ANSWER: Abbott denies the allegations of paragraph 445.

446. As a direct and proximate result of Defendants' wrongful actions and failure to test, Plaintiff suffered from significant pain; suffering; permanent, profound and debilitating conditions including but not limited to renal failure and renal injuries and/or death; and economic damages incurred through the treatment for the renal failure and renal injuries and/or death caused by PPI Product use.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 446.

COUNT VII
BREACH OF EXPRESS WARRANTY

448. Plaintiff repeats, reiterates, and re-alleges each and every preceding allegation of this Complaint with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein⁵.

449. Defendants expressly warranted that their PPIs were safe for their intended use, ingesting the product, to treat the targeted indication, GERD (or heartburn), as set forth more fully herein.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 449.

450. At the time Defendants made the express warranties described herein, Defendants had knowledge of the manner in which PPIs were to be used—by ingestion, and the purpose for which the PPIs were to be used—to treat heartburn, and Defendants expressly warranted PPIs to be in all respects safe, effective, and proper for such manner and purpose of use.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 450.

⁵ Plaintiff's Complaint omits Paragraph 447.

451. Defendants' PPIs failed to conform to these express representations, including, but not limited to, the express representation that PPIs were safe for their intended use of ingesting the product to treat heartburn, and the express representation that PPIs posed no increased risk to individuals with "Renal Insufficiency," as set forth more fully herein.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 451.

452. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Administration Options" Section for the delayed-release capsule version of the product stated, "Capsule can be swallowed whole" or "Capsule can be opened and mixed with applesauce" for oral consumption. Additionally, the labeling stated the delayed-release capsule version of the product can be "opened and intact granules emptied into a syringe and delivered through the nasogastric tube." In short, Defendants' labeling expressly instructed users it was safe to use the delayed-release capsule version of the product by ingesting it.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 452.

453. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Administration Options" Section for the delayed-release oral suspension version of the product stated, "Mix contents of packet with 1 tablespoon (15 mL) of water, leave 2 to 3 minutes to thicken, stir and drink within 30 minutes." Additionally, the labeling stated the delayed-release oral suspension version of the product can be prepared as above and "inject[ed] through the nasogastric or gastric tube within 30 minutes." In short, Defendants' labeling expressly instructed users it was safe to use the delayed-release oral suspension version of the product by ingesting it.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 453.

454. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Adverse Reactions" Section contained a "Clinical Trials Experience" subsection, stating that the "safety" of the product had been evaluated for the treatment of "GERD" (heartburn), and that adverse side-effects had been noted including, but not limited to, diarrhea, headache, and somnolence. Notably, there is no mention whatsoever in the labeling's "Adverse Reactions" section of kidney/renal injury, not even in the subsection for "additional adverse reactions ... with an incidence <1%[.]" Additionally, the labeling specifically states "no new safety concerns" were raised by the clinical trials. Thus, Defendants' labeling expressly warranted by omission that the

product was safe for the use of ingesting the product for treatment of heartburn with no increased risk of kidney injury.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 454.

455. In expressly warranting their product as safe for ingestion, Defendants expressly warranted that their product was safe for the user's internal organs, especially their kidneys, since kidney injuries did not appear in any of the labeling sections relating to clinically-studied adverse side effects, as set forth above.

ANSWER: Abbott denies the allegations of paragraph 455.

456. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Special Populations" Section contained a sub-grouping for individuals with "Renal Insufficiency," under which the labeling stated: "No dosage adjustment necessary." Thus, Defendants expressly warranted the product as safe for its intended use of ingesting the product to treat heartburn *specifically* in patients who already had renal insufficiency, and who thus were at an even higher risk of developing serious kidney injury from PPI use.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 456.

457. At all times during the relevant period, each and every Defendant's product labeling for PPIs contained the following express statement(s) or substantially identical variant(s) thereof: the "Special Populations" Section contained a sub-grouping for individuals with "Renal Insufficiency," under which the labeling stated: "The pharmacokinetics of [PPIs] in patients with renal impairment are not expected to be altered relative to healthy volunteers as less than 1% of esomeprazole is excreted unchanged in urine." Thus, Defendants expressly warranted the product as safe for its intended use of ingesting the product to treat heartburn specifically in patients who already had renal impairment, and who thus were at an even higher risk of developing serious kidney injury from PPI use.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the FDA-approved product labeling speaks for itself. Abbott denies the remaining allegations of paragraph 457.

458. In expressly warranting their product as safe for use even by individuals who had renal insufficiency or renal impairment, it naturally follows that Defendants expressly warranted their product as safe for use by individuals who did not have renal insufficiency or renal impairment.

ANSWER: Abbott denies the allegations of paragraph 458.

459. In expressly warranting their product as safe for use even by individuals who had renal insufficiency or renal impairment, Defendants expressly warranted that using PPIs as intended—ingesting them to treat heartburn—carried no increased risk of serious renal (kidney) injury.

ANSWER: Abbott denies the allegations of paragraph 459.

460. Defendants' express warranties were part of the basis for Plaintiff's PPI use, as Plaintiff relied on Defendants' express warranties in deciding to use PPIs.

ANSWER: Abbott denies the allegations of paragraph 460.

461. Defendants' breached their express warranties as described herein because PPIs are not safe to ingest and, to the contrary, produce serious side effects to users' internal organs, including their kidneys.

ANSWER: Abbott denies the allegations of paragraph 461.

462. As a result of the foregoing breaches of express warranties, the Plaintiff herein was caused to suffer serious kidney injuries, as well as other severe and personal injuries that are permanent and lasting in nature, including physical pain and mental anguish, diminished enjoyment of life, a risk of future kidney injuries, a reasonable fear of future decline in kidney function, any and all life complications caused by Plaintiff's existing kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above health consequences.

ANSWER: Abbott denies the allegations of paragraph 462.

463. As a result of the foregoing breaches of express warranties, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment as compared with prior to Plaintiff's use of Defendants' PPI drugs.

ANSWER: Abbott denies the allegations of paragraph 463.

COUNT VIII **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

464. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint with the same force and effect as if set forth fully herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

465. Defendants, as large pharmaceutical corporations, are merchants with respect to the kind of goods that includes PPIs—pharmaceuticals, and thus it is reasonably expected and assumed by purchasers of Defendants' products that Defendants' pharmaceutical products, including PPIs,

are safe for their ordinary purpose of being ingested to treat a particular medical condition.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no answer is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 465.

466. At all times herein mentioned, the Defendants manufactured, compounded, distributed, recommended, merchandized, advertised, promoted and sold PPIs for the ordinary purpose of ingesting PPIs to treat heartburn.

ANSWER: Abbott admits that, at various times in the past, Abbott packaged, marketed and/or promoted Prevacid®, and at various times in the past, Prevacid® was distributed from Abbott-owned distribution centers. Abbott further admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott specifically denies that it manufactured Prevacid® and further denies the remaining allegations of paragraph 466.

467. As merchants of PPIs, Defendants impliedly represented and warranted to the users of PPIs, including Plaintiff, that PPIs were of merchantable quality and safe for such ordinary purpose of ingesting PPIs to treat heartburn.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 467.

468. These aforementioned representations and warranties were false, misleading, and inaccurate because PPIs were unsafe, unreasonably dangerous, and were not of merchantable quality, consequently degrading Plaintiff's health.

ANSWER: Abbott denies the allegations of paragraph 468.

469. PPIs were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products were expected to reach and did reach users, handlers, and persons, including Plaintiff, that came into contact with said products without

any substantial change in the condition in which they were sold.

ANSWER: Abbott admits that Prevacid® was expected to reach intended consumers without substantial change in the condition in which it was distributed. Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegation of this paragraph that Prevacid® “did reach” users without substantial change in the condition in which it was distributed, and therefore denies them. Abbott denies the remaining allegations of paragraph 469, and specifically denies that Prevacid® is or was defective, unsafe, or inherently dangerous.

470. Plaintiff and members of the medical community relied on Defendants’ implied warranty of merchantability in deciding to use PPIs for the ordinary purpose of ingesting PPIs to treat heartburn.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 470.

471. Plaintiff reasonably relied upon the skill and judgment of Defendants with respect to whether PPIs were safe and fit for the ordinary purpose for which they were intended as described herein.

ANSWER: Abbott denies the allegations of paragraph 471.

472. Defendants breached the aforesaid implied warranty of merchantability as PPIs were not fit for their ordinary purpose for which such goods are used, and in fact had an unreasonable risk of harm to internal organs, specifically, the kidneys.

ANSWER: Abbott denies the allegations of paragraph 472.

473. Upon discovering the connection between Plaintiff’s ordinary use of Defendants’ PPIs and Plaintiff’s resultant kidney injury, Plaintiff provided notice to Defendants of Defendants’ breach of implied warranty of merchantability by filing this lawsuit.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies any remaining allegations of paragraph 473.

474. As a result of the foregoing breach of implied warranty of merchantability, the

Plaintiff was caused to suffer serious and dangerous side effects, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, a risk of future kidney injuries, reasonable fear of future kidney function decline, any and all life complications caused by Plaintiff's kidney injuries, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above and other named health consequences.

ANSWER: Abbott denies the allegations of paragraph 474.

475. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

ANSWER: Abbott denies the allegations of paragraph 475.

COUNT IX **NEGLIGENT MISREPRESENTATION**

476. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

477. From the time Defendants' PPI Products were first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that PPI Products were safe and effective for the treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 477.

478. At all times mentioned, Defendants conducted sales and marketing campaigns to promote the sale, use and overuse of their PPI Products and willfully deceived Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 478.

479. Defendants had a duty to ensure that the representations they made about their PPI Products were true and complete when made. Defendants made the foregoing representation

without any reasonable ground for believing them to be true.

ANSWER: Abbott states that the allegations of this paragraph regarding duty constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 479.

480. At all relevant times hereto, Defendants conducted sales and marketing campaigns to promote the sale of their PPI Products and deceived patients, consumers, physicians and healthcare providers, including the Plaintiff and Plaintiff's healthcare providers, as to the health risks and consequences of the use of their PPI Products.

ANSWER: Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 480.

481. The Defendants made these false and misleading representations without any reasonable ground for believing them to be true concerning the safety and efficacy of PPI Products for treatment of peptic disorders, including GERD, peptic ulcer disease and nonsteroidal anti-inflammatory drug-induced gastropathy.

ANSWER: Abbott denies the allegations of paragraph 481.

482. These representations were made directly by Defendants, their sales representatives and other authorized agents of the Defendants to physicians and other healthcare providers; in television media directed towards the general public; in publications, the popular press, and other written materials which were directed to physicians, patients, consumers and the general public; and on Internet websites and applications directed to consumers and physicians, including the Plaintiff, with the intention of inducing and influencing the demand for, as well as the ultimate prescription, purchase and use of their PPI Products.

ANSWER: Abbott admits that, at various times in the past, it marketed and/or promoted Prevacid® in the United States. Abbott denies the remaining allegations of paragraph 482.

483. The representations by the Defendants were in fact false, in that their PPI Products are not safe, fit and/or effective for human consumption as labeled, using PPIs Products is hazardous to consumers' health, and PPI Products have a serious propensity to cause serious injuries to users, including but not limited to the kidney and related personal injuries suffered by Plaintiff.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further

denies the remaining allegations of paragraph 483.

484. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of PPI Products.

ANSWER: Abbott denies the allegations of paragraph 484.

485. In reliance on the misrepresentations by the Defendants, Plaintiff was induced to purchase and use PPI Products. If Plaintiff had known the truth and the facts concealed by the Defendants, Plaintiff would not have used the PPI Products or would have used far fewer PPI Products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know all of the facts.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's purchase and use of PPI Products, and therefore denies them. Abbott denies the remaining allegations of paragraph 485.

486. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries (in some cases death), which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 486.

487. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 487.

COUNT X
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant Abbott)

488. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

489. As a result of Defendant Abbott's research and testing, or lack thereof, Defendant Abbott blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that Defendant Abbott's PPIs were safe and effective for use.

ANSWER: Abbott denies the allegations of paragraph 489.

490. As a result of Defendant Abbott's research and testing, or lack thereof, Defendant Abbott intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

ANSWER: Abbott denies the allegations of paragraph 490.

491. Defendant Abbott had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

ANSWER: Abbott states that the allegations of this paragraph constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, it admits that it complied with its duty under the law at all times. Abbott denies the remaining allegations of paragraph 491.

492. The information distributed to the public, the FDA, and the Plaintiff by Defendant Abbott, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Abbott denies the allegations of paragraph 492.

493. The information distributed to the public, the FDA, and the Plaintiff by Defendant Abbott intentionally included representations that Defendant Abbott's PPIs were safe and effective.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 493.

494. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant

Abbott intentionally included representations that Defendant Abbott's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 494.

495. The information distributed to the public, the FDA, and the Plaintiff, by Defendant Abbott intentionally included representations that Defendant Abbott's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with PPIs.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 495.

496. The information distributed to the public, the FDA, and the Plaintiff, by Defendant Abbott intentionally included false representations that PPIs were not injurious to the health and/or safety of its intended users.

ANSWER: Abbott denies the allegations of paragraph 496.

497. These representations were all false and misleading.

ANSWER: Abbott denies the allegations of paragraph 497.

498. Upon information and belief, Defendant Abbott intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that PPIs were not safe for its intended use.

ANSWER: Abbott denies the allegations of paragraph 498.

499. Defendant Abbott intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of PPIs, specifically but not limited to Defendant Abbott's PPIs not having dangerous and serious health and/or safety concerns.

ANSWER: Abbott denies the allegations of paragraph 499.

500. That it was the purpose of Defendant Abbott in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for

use of PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

ANSWER: Abbott denies the allegations of paragraph 500.

501. Defendant Abbott made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that PPIs were fit and safe for its intended use.

ANSWER: Abbott denies the allegations of paragraph 501.

502. Defendant Abbott made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant Abbott's PPIs were fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

ANSWER: Abbott denies the allegations of paragraph 502.

503. The Defendant Abbott made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant Abbott's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

ANSWER: Abbott denies the allegations of paragraph 503.

504. That these representations and others made by Defendant Abbott were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Abbott denies the allegations of paragraph 504.

505. That these representations and others, made by Defendant Abbott, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant Abbott's PPIs.

ANSWER: Abbott denies the allegations of paragraph 505.

506. The Defendant Abbott, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Abbott denies the allegations of paragraph 506, and further denies that Prevacid® is dangerous or defective.

507. That Defendant Abbott willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant Abbott's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Abbott denies the allegations of paragraph 507.

508. Defendant Abbott, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Abbott admits that Prevacid® is FDA-approved and that the mechanism of action and approved indications are outlined in the FDA-approved product labeling, which speaks for itself. Abbott denies the remaining allegations of paragraph 508.

509. Defendant Abbott utilized direct to consumer advertising to market, promote, and/or advertise Defendant Abbott's PPIs.

ANSWER: Abbott denies the allegations of paragraph 509.

510. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendant Abbott's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant Abbott's PPIs.

ANSWER: Abbott denies the allegations of paragraph 510.

511. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs.

ANSWER: Abbott denies the allegations of paragraph 511.

512. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant Abbott, nor could the Plaintiff with reasonable diligence have discovered the true facts.

ANSWER: Abbott denies the allegations of paragraph 512.

513. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant Abbott's PPIs, Plaintiff would not have purchased, used and/or relied on Defendant's PPIs.

ANSWER: Abbott denies the allegations of paragraph 513.

514. That the Defendant Abbott's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

ANSWER: Abbott denies the allegations of paragraph 514.

515. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 515.

516. Defendant Abbott's conduct, as described herein, was extreme and outrageous. Defendant Abbott risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant Abbott made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 516.

517. To this day, Abbott continues to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant Abbott's PPIs cause to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 517.

COUNT -XI
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TPUSA)

518. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

519. Defendant TPUSA conducted research and used PPIs as part of its research.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 519, and therefore denies them.

520. As a result of Defendant TPUSA's research and testing, or lack thereof, Defendant TPUSA blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPUSA's PPIs were safe and effective for use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 520, and therefore denies them.

521. As a result of Defendant TPUSA's research and testing, or lack thereof, Defendant TPUSA intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 521, and therefore denies them.

522. Defendant TPUSA had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 522, and therefore denies them.

523. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPUSA, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 523, and therefore denies them.

524. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs was safe and effective.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 524, and therefore denies them.

525. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 525, and therefore denies them.

526. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPUSA intentionally included representations that Defendant TPUSA's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of Prevacid in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Prevacid.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 526, and therefore denies them.

527. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPUSA intentionally included false representations that Defendant TPUSA's PPIs was not injurious to the health and/or safety of its intended users.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 527, and therefore denies them.

528. These representations were all false and misleading.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 528, and therefore denies them.

529. Upon information and belief, Defendant TPUSA intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPUSA's PPIs was not safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 529, and therefore denies them.

530. Defendant TPUSA intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPUSA's PPIs, specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 530, and therefore denies them.

531. That it was the purpose of Defendant TPUSA in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPUSA's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Defendant TPUSA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 531, and therefore denies them.

532. Defendant TPUSA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPUSA's PPIs was fit and safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 532, and therefore denies them.

533. Defendant TPUSA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPUSA's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 533, and therefore denies them.

534. Defendant TPUSA made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TPUSA's

PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 534, and therefore denies them.

535. That these representations and others made by Defendant TPUSA were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 535, and therefore denies them.

536. That these representations and others, made by Defendant TPUSA, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPUSA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 536, and therefore denies them.

537. Defendant TPUSA, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 537, and therefore denies them.

538. That Defendant TPUSA willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPUSA's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 538, and therefore denies them.

539. Defendant TPUSA, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 539, and therefore denies them.

540. Defendant TPUSA utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPUSA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 540, and therefore denies them.

541. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPUSA' [sic] representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant

TPUSA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 541, and therefore denies them.

542. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 542, and therefore denies them.

543. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPUSA, nor could the Plaintiff with reasonable diligence have discovered the true facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 543, and therefore denies them.

544. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPUSA's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 544, and therefore denies them.

545. That Defendant TPUSA's aforementioned conduct constitutes fraud and fraudulent

misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 545, and therefore denies them.

546. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 546.

547. Defendant TPUSA's conduct, as described herein, was extreme and outrageous. Defendant TPUSA risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPUSA made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 547, and therefore denies them.

548. To this day, Defendant TPUSA continue [sic] to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPUSA's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 548, and therefore denies them.

COUNT -XII
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TPA)

549. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

550. Defendant TPA conducted research and used PPIs as part of its research.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 550, and therefore denies them.

551. As a result of Defendant TPA's research and testing, or lack thereof, Defendant TPA blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPA's PPIs was safe and effective for use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 551, and therefore denies them.

552. As a result of Defendant TPA's research and testing, or lack thereof, Defendant TPA intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 552, and therefore denies them.

553. Defendant TPA had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 553, and therefore denies them.

554. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPA, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 554, and therefore denies them.

555. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPA intentionally included representations that Defendant TPA's PPIs was safe and effective.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 555, and therefore denies them.

556. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TPA intentionally included representations that Defendant TPA's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 556, and therefore denies them.

557. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPA intentionally included representations that Defendant TPA's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of Defendant TPA's PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 557, and therefore denies them.

558. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPA intentionally included false representations that Defendant TPA's PPIs was not injurious to the health and/or safety of its intended users.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 558, and therefore denies them.

559. These representations were all false and misleading.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 559, and therefore denies them.

560. Upon information and belief, Defendant TPA intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPA's PPIs was not safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 560, and therefore denies them.

561. Defendant TPA intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPA's PPIs specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 561, and therefore denies them.

562. That it was the purpose of Defendant TPA in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPA's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 562, and therefore denies them.

563. Defendant TPA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPA's PPIs was fit and safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 563, and therefore denies them.

564. Defendant TPA made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPA's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 564, and therefore denies them.

565. Defendant TPA made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Prevacid did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 565, and therefore denies them.

566. That these representations and others made by Defendant TPA were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 566, and therefore denies them.

567. That these representations and others, made by Defendant TPA, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 567, and therefore denies them.

568. Defendant TPA, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 568, and therefore denies them.

569. That Defendant TPA willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPA's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 569, and therefore denies them.

570. Defendant TPA, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 570, and therefore denies them.

571. Defendant TPA utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 571, and therefore denies them.

572. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPA' [sic] representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 572, and therefore denies them.

573. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 573, and therefore denies them.

574. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPA, nor could the Plaintiff with reasonable diligence have discovered the true facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 574, and therefore denies them.

575. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPA's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 575, and therefore denies them.

576. That Defendant TPA's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 576, and therefore denies them.

577. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 577.

578. Defendant TPA's conduct, as described herein, was extreme and outrageous. Defendant TPA risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPA made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 578, and therefore denies them.

579. To this day, Defendant TPA continue [sic] to engage in outrageous conduct with reckless disregard for the safety of the consumer, including Plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPA's PPIs causes to the kidney and continues to make a conscious decision

not to redesign, relabel, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 579, and therefore denies them.

COUNT -XIII
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TDC)

580. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

581. Defendant TDC conducted research and used PPIs as part of its research.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 581, and therefore denies them.

582. As a result of Defendant TDC's research and testing, or lack thereof, Defendant TDC blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TDC's PPIs was safe and effective for use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 582, and therefore denies them.

583. As a result of Defendant TDC's research and testing, or lack thereof, Defendant TDC intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare

professionals, the FDA, and other regulatory bodies.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 583, and therefore denies them.

584. Defendant TDC had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 584, and therefore denies them.

585. The information distributed to the public, the FDA, and the Plaintiff by Defendant TDC, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 585, and therefore denies them.

586. The information distributed to the public, the FDA, and the Plaintiff by Defendant TDC intentionally included representations that Defendant TDC's PPIs was safe and effective.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 586, and therefore denies them.

587. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant

TDC intentionally included representations that Defendant TDC's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 587, and therefore denies them.

588. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TDC intentionally included representations that Defendant TDC's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 588, and therefore denies them.

589. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TDC intentionally included false representations that PPIs were not injurious to the health and/or safety of its intended users.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 589, and therefore denies them.

590. These representations were all false and misleading.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 590, and therefore denies them.

591. Upon information and belief, Defendant TDC intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TDC's PPIs were not safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 591, and therefore denies them.

592. Defendant TDC intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of PPIs, specifically but not limited to Defendant TDC's PPIs not having dangerous and serious health and/or safety concerns.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 592, and therefore denies them.

593. That it was the purpose of Defendant TDC in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TDC's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 593, and therefore denies them.

594. Defendant TDC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TDC's PPIs were fit and safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 594, and therefore denies them.

595. Defendant TDC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TDC's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 595, and therefore denies them.

596. Defendant TDC made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TDC's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 596, and therefore denies them.

597. That these representations and others made by Defendant TDC were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 597, and therefore denies them.

598. That these representations and others, made by Defendant TDC, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective

healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TDC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 598, and therefore denies them.

599. Defendant TDC, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TDC's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 599, and therefore denies them.

600. That Defendant TDC willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TDC's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 600, and therefore denies them.

601. Defendant TDC, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 601, and therefore denies them.

602. Defendant TDC utilized direct to consumer advertising to market, promote, and/or advertise Defendant TDC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 602, and therefore denies them.

603. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TDC's representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TDC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 603, and therefore denies them.

604. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TDC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 604, and therefore denies them.

605. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TDC, nor could the Plaintiff with reasonable diligence have discovered the true facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 605, and therefore denies them.

606. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 606, and therefore denies them.

607. That Defendant TDC's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 607, and therefore denies them.

608. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 608.

609. Defendant TDC's conduct, as described herein, was extreme and outrageous. Defendant TDC risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TDC made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 609, and therefore denies them.

610. To this day, Defendant TDC continue [sic] to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TDC's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 610, and therefore denies them.

COUNT –XIV
FRAUD AND FRAUDULENT MISREPRESENTATION
(As to Defendant TPC)

611. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in the paragraphs above, with the same force and effect as if fully set forth herein.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

612. Defendant TPC conducted research and PPIs as part of its research [sic].

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 612, and therefore denies them.

613. As a result of Defendant TPC's research and testing, or lack thereof, Defendant TPC blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that Defendant TPC's PPIs was safe and effective for use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 613, and therefore denies them.

614. As a result of Defendant TPC's research and testing, or lack thereof, Defendant TPC intentionally omitted certain results of testing and research to the Plaintiff, public, healthcare professionals, the FDA, and other regulatory bodies.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 614, and therefore denies them.

615. Defendant TPC had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as her respective healthcare providers and/or the FDA.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 615, and therefore denies them.

616. The information distributed to the public, the FDA, and the Plaintiff by Defendant TPC, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 616, and therefore denies them.

617. The information distributed to the public, the FDA, and the Plaintiff by Defendant

TPC intentionally included representations that Defendant TPC's PPIs was safe and effective.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 617, and therefore denies them.

618. The information distributed to the public, the FDA, and the Plaintiffs, by Defendant TPC intentionally included representations that Defendant TPC's PPIs carried the same risks, hazards, and/or dangers as other classes of medication used to treat acid reflux.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 618, and therefore denies them.

619. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPC intentionally included representations that Defendant TPC's PPIs was more effective in treating the symptoms of acid reflux than other forms of medication, encouraging the use of PPIs in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risks associated with Defendant TPC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 619, and therefore denies them.

620. The information distributed to the public, the FDA, and the Plaintiff, by Defendant TPC intentionally included false representations that Defendant TPC's PPIs was not injurious to the health and/or safety of its intended users.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 620, and therefore denies them.

621. These representations were all false and misleading.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 621, and therefore denies them.

622. Upon information and belief, Defendant TPC intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that Defendant TPC's PPIs was not safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 622, and therefore denies them.

623. Defendant TPC intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of Defendant TPC's PPIs, specifically but not limited to PPIs not having dangerous and serious health and/or safety concerns.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 623, and therefore denies them.

624. That it was the purpose of Defendant TPC in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of Defendant TPC's PPIs and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 624, and therefore denies them.

625. Defendant TPC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPC's PPIs was fit and safe for its intended use.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 625, and therefore denies them.

626. Defendant TPC made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that Defendant TPC's PPIs was fit and safe for its intended use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of acid reflux medication.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 626, and therefore denies them.

627. Defendant TPC made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and to the Plaintiff that Defendant TPC's PPIs did not present health and/or safety risks and did not have any negative effects on kidney function in patients ingesting the Defendant's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 627, and therefore denies them.

628. That these representations and others made by Defendant TPC were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 628, and therefore denies them.

629. That these representations and others, made by Defendant TPC, were made with the intention of deceiving and defrauding the Plaintiff, including her respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/re prescribe Defendant TPC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 629, and therefore denies them.

630. Defendant TPC, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 630, and therefore denies them.

631. That Defendant TPC willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on Defendant TPC's PPIs and/or that her respective healthcare providers would dispense, prescribe, and/or recommend the same.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott

lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 631, and therefore denies them.

632. Defendant TPC, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 632, and therefore denies them.

633. Defendant TPC utilized direct to consumer advertising to market, promote, and/or advertise Defendant TPC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 633, and therefore denies them.

634. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe Defendant TPC' [sic] representations to be true at the time they were made and relied upon the representations and were thereby induced to purchase, use and rely on Defendant TPC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 634, and therefore denies them.

635. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 635, and therefore denies them.

636. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant TPC, nor could the Plaintiff with reasonable diligence have discovered the true facts.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 636, and therefore denies them.

637. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of Defendant TPC's PPIs, Plaintiff would not have purchased, used and/or relied on Defendants' PPIs.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 637, and therefore denies them.

638. That Defendant TPC's aforementioned conduct constitutes fraud and fraudulent misrepresentation, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 638, and therefore denies them.

639. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal

injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies the allegations of paragraph 639.

640. Defendant TPC's conduct, as described herein, was extreme and outrageous. Defendant TPC risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendant TPC made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 640, and therefore denies them.

641. To this day, Defendant TPC continue [sic] to engage in outrageous conduct with reckless disregard for the safety of the consumer, including plaintiff, by misleading and defrauding the public, Plaintiff, and/or Plaintiff's healthcare providers by continuing to deny the negative effects that Defendant TPC's PPIs causes to the kidney and continues to make a conscious decision not to redesign, relabel, warn or inform the unsuspecting consuming public.

ANSWER: Abbott states that the allegations of this paragraph do not state any allegations as to Abbott and, therefore, no answer by Abbott is required. If an answer is required, Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 641, and therefore denies them.

COUNT XV **GROSS NEGLIGENCE**

1000. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident States [sic].⁶

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as

⁶ Plaintiff's Complaint omits paragraphs 642 through 999.

if fully set forth herein.

1001. The wrong done by the Defendants was aggravated by the kind of malice, fraud, reckless disregard for the rights of others, the public and the Plaintiff and conduct for which the law allows the imposition of exemplary damages, in that the Defendants' conduct:

- a. when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or
- b. Defendants made a material representation that was false, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation be acted on by Plaintiff, and Plaintiff relied on the representation and suffered injury as a result of this reliance.

ANSWER: Abbott denies the allegations of paragraph 1001, including all subparts.

1002. Plaintiff, therefore, seeks exemplary damages in an amount within the jurisdictional limits of the court. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence which proximately caused the injuries to Plaintiff. In that regard, Plaintiff seeks exemplary damages in an amount which would punish such Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

ANSWER: Abbott admits that Plaintiff seeks damages and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of paragraph 1002.

COUNT XVI
VIOLATION OF CONSUMER PROTECTION LAWS
AND DECEPTIVE TRADE PRACTICES

1003. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Plaintiff's resident State.

ANSWER: Abbott incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

1004. Plaintiff used Defendants' PPI Products and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

ANSWER: Abbott lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph regarding Plaintiff's use of PPI Products and therefore denies them. Abbott denies the remaining allegations of paragraph 1004.

1005. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of the consumer protection law, 815 ILCS 505/1.

ANSWER: Abbott states that the allegations of paragraph 1005 constitute legal conclusions to which no response is required. To the extent that these allegations are construed as factual allegations directed to Abbott, Abbott denies them.

1006. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects, including serious kidney injuries and other severe and personal injuries, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life and financial expenses for hospitalization and medical care.

ANSWER: Abbott denies that Prevacid® causes kidney or other injuries, and further denies the remaining allegations of paragraph 1006.

1007. Defendants' conduct, as described herein, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems with their drugs and suppressed this knowledge from the general public, Plaintiff, and/or Plaintiff's healthcare providers. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

ANSWER: Abbott denies the allegations of paragraph 1007.

PLAINTIFF'S PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, discomfort, physical impairment, emotional distress, loss of enjoyment of life, loss of consortium, wrongful death and other noneconomic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;
- c. Prejudgment interest;
- d. Post-judgment interest;

- e. Awarding reasonable attorneys' fees;
- f. Awarding the costs of these proceedings; and
- g. Such other and further relief as this Court deems just and proper.

ANSWER: Abbott admits that Plaintiff seeks judgment, damages, and other relief, but denies that Plaintiff is entitled to judgment, damages, or relief of any kind. Abbott further denies the remaining allegations of Plaintiff's Prayer for Relief.

AFFIRMATIVE AND OTHER DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Abbott in this matter. Abbott therefore asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if facts warrant, Abbott may withdraw any of these defenses as may be appropriate. Further, Abbott reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Abbott states as follows:

1. Plaintiff's Complaint against Abbott fails to state a claim upon which relief may be granted.
2. This Court lacks personal jurisdiction over Abbott with respect to Plaintiff's claims, and thus the Complaint should be dismissed.
3. Each and every claim alleged or raised in the Complaint is barred by the applicable statute of limitations, the applicable statute of repose, the doctrine of prescription, and/or is otherwise untimely.
4. Each and every claim alleged or raised in the Complaint is barred by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider and Abbott's only obligation, if any, would be to warn the prescribing health care provider, which obligation was fulfilled.

5. Abbott gives notice that, to the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Abbott intends to rely upon same in defense of this action.

6. Each and every claim alleged or raised in the Complaint is barred by the doctrines of laches, estoppel, waiver, and/or statutory and regulatory compliance.

7. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening and/or supervening cause or causes, and any act or omission on the part of Abbott was not the proximate and/or competent producing cause of such alleged injuries and damages.

8. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses may have been caused, may have been solely caused, may be barred, and/or may be limited in whole or in part by the contributory negligence or comparative fault and/or comparative negligence of Plaintiff.

9. In the alternative, without waiving its denial of liability to Plaintiff, Abbott states that, assuming that 100% represents the total combined fault of the parties to this action, the fault on the part of Plaintiff was more than 50% of the total proximate cause of the alleged injuries and, therefore, there is no liability on the part of Abbott. In the alternative, in the event that it is found that fault on the part of Plaintiff is less than 50% of the proximate cause of the alleged injury, then the amount of the verdict awarded to Plaintiff must be reduced in accordance with the percentage of that fault.

10. If Plaintiff has sustained injuries or losses, as alleged in the Complaint, Plaintiff's claims regarding such injuries or losses may be barred or reduced by Plaintiff's knowingly, voluntarily,

and/or willfully assuming the risk of any injury as the result of the consumption of, administration of, or exposure to the product at issue or any medicine or pharmaceutical preparation manufactured or distributed by another manufacturer.

11. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Abbott and over whom Abbott had no control and for whom Abbott may not be held accountable.

12. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by circumstances, events, or persons over whom Abbott had no authority or control and for which Abbott is not answerable in damages to Plaintiff.

13. To the extent Plaintiff's claims were caused by the actions, omissions, or products of persons or entities over whom Abbott has no dominion, authority, or control, Abbott is entitled to have its liability to the Plaintiff, if any, reduced as a result of the fault or negligence of said persons or entities, pursuant to governing law.

14. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by an unforeseeable material and substantial alteration, change, improper handling, or misuse or abuse of the product at issue after it left the control of Abbott.

15. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were the result of unavoidable circumstances that could not have been prevented by any person, including Abbott.

16. Abbott denies any liability, but if Abbott is ultimately found liable to Plaintiff, then Abbott

shall only be liable for its equitable share of Plaintiff's recovery since any such liability would be insufficient to impose joint liability.

17. If Plaintiff recovers from Abbott, Abbott is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence of fault proximately caused or contributed to cause Plaintiff's alleged damages.

18. Any verdict of judgment rendered against Abbott must be reduced by the comparative fault of other persons or entities.

19. Any verdict of judgment rendered against Abbott must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part for any past or future loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

20. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by the off-label use of the product at issue that Abbott did not proscribe and for which Abbott is not legally responsible.

21. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated physical, physiological, medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions, or natural courses of conditions for which Abbott is not legally responsible.

22. Plaintiff's Complaint fails to state a claim upon which relief can be granted as to costs, attorney's fees, expert fees, expenses, pre-judgment interest, post-judgment interest, refund, rescission, unjust enrichment, disgorgement, or restitution.

23. Plaintiff did not detrimentally rely on any labeling, warnings, or information concerning Prevacid®.

24. Any warranties made by Abbott to Plaintiff were disclaimed.

25. To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are barred for lack of timely notice of any breach or alleged failure.

26. Abbott did not sell or distribute Prevacid® directly to Plaintiff, and Plaintiff did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiff's claims are therefore barred by lack of privity.

27. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

28. Any claim for breach of express warranty must fail because Plaintiff failed to allege any representations about the product at issue giving rise to an express warranty.

29. Plaintiff's Complaint fails to state a claim upon which relief can be granted against Abbott in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of Prevacid®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

30. Plaintiff cannot establish that any reasonable alternative design would have rendered the product at issue safer overall, and that the failure to adopt a reasonable alternative design rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

31. Plaintiff cannot establish that any reasonable alternative instructions or warnings concerning foreseeable risks of harm posed by the product at issue would have rendered the product safer overall, and that the failure to provide such alternative instructions or warnings

rendered the product at issue not reasonably safe, in accordance with the Restatement (Third) of Torts: Products Liability.

32. Each and every claim alleged or raised in the Complaint is barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

33. Each and every claim alleged or raised in the Complaint is barred in whole or in part because legally adequate "directions or warnings" were provided as to the use of the product at issue and any other medicine or pharmaceutical preparation to which Plaintiff attribute Plaintiff's alleged damages within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

34. Each and every claim alleged or raised in the Complaint is barred by Section 4, et seq., of the Restatement (Third) of Torts: Products Liability.

35. Each and every claim alleged or raised in the Complaint is barred by comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

36. Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of the product at issue.

37. Any claims by Plaintiff relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First and Fourteenth Amendment rights to petition the government, and/or the *Noerr-Pennington* doctrine.

38. Each and every claim alleged or raised in the Complaint is barred in whole or in part by Plaintiff's failure to mitigate alleged damages.

39. Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegate their claims to negligence.

40. All activities of Abbott as alleged in the Complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to any alleged misrepresentations or omissions are barred.

41. Each and every claim alleged or raised in the Complaint is barred because, if the product at issue was unsafe, which Abbott denies, then it was unavoidably unsafe as defined in the Restatement of Torts. The apparent benefits of the product exceeded any apparent risk, given the scientific knowledge available when the product was marketed.

42. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical product at issue provide net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

43. Plaintiff, or Plaintiff's physicians, were aware or should have been aware of any potential hazards reported to be associated with the use of Prevacid® and appreciated or should have appreciated these potential hazards based, in part, on the directions, information, and warnings.

44. Plaintiff's claims are barred because Prevacid® was consistent with and exceeded consumer expectations.

45. Plaintiff's claims purportedly asserted under statutes and regulations relating to prescription drugs fail, in whole or in part, because these statutes and regulations do not contain or create any private cause of action.

46. Abbott had a good faith belief in the lawfulness of its actions.

47. The advertisements and labeling with respect to the product at issue were not false or misleading and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution and the state Constitution.

48. The public interest in the benefit and availability of the product at issue precludes liability for risks, if any, resulting from any activities undertaken by Abbott, that were unavoidable, given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product at issue, then such risk, if any, is outweighed by the benefit of the product.

49. Plaintiff's failure to warn claim is barred given that Abbott had no duty to warn of risks of which Abbott neither knew nor should have known at the time Prevacid® was designed, distributed, and manufactured.

50. At all relevant times, Prevacid® was manufactured and distributed in a reasonable and prudent manner, based upon available medical and scientific knowledge, and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

51. To the extent there were any risks associated with the use of Prevacid® that Abbott knew or should have known and that gave rise to a duty to warn, which Abbott denies, Abbott at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

52. Applicable law does not recognize a post-sale duty to warn in the present circumstances. Accordingly, the Complaint fails to state a claim upon which relief may be granted for inadequate post-sale marketing or post-sale duty to warn.

53. Each and every claim alleged or raised in the Complaint may be barred because Plaintiff has failed to comply with the conditions precedent or subsequent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

54. Each and every claim alleged or raised in the Complaint may be barred in whole or in part by the doctrine of informed consent.

55. Plaintiff's damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiff as a result of any insurance or other health benefits plan, or any amounts paid for by any insurance, other health benefits plan, or other collateral sources.

56. To the extent that Plaintiff's Complaint seeks recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action under applicable law.

57. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Abbott, if any, should be reduced accordingly.

58. Plaintiff's claims may be barred, in whole or in part, due to res judicata, collateral estoppel, or release of claims.

59. Plaintiff's Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

60. Plaintiff's Complaint fails to state a claim for fraud, misrepresentation, or suppression.

61. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Abbott and all of its activities with respect to the product at issue have been and are conducted under the supervision of the FDA.

62. Each and every claim alleged or raised in the Complaint and based on allegedly inadequate warnings is barred even if Abbott failed to provide adequate warnings with respect to known or potential dangers or risks associated with the use of the product, because physicians prescribing the product at issue either knew or should have known of the potential or known dangers or risks, and there is no duty to warn members of a profession against dangers known or that should be known to members of the profession.

63. Any injuries or damages Plaintiff may have sustained may have been caused by a substantial change in the product at issue after leaving the possession, custody, and control of Abbott, if applicable.

64. The common law claims and theories of liability set forth in the Complaint are barred by the doctrine of federal preemption. Abbott's conduct conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, each and every claim alleged or raised in the Complaint is barred in whole or in part under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

65. The New Drug Application for Prevacid® was approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such statutes and regulations by Abbott, as applicable, demonstrates that Prevacid® was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiff's claims against Abbott. Compliance with any applicable statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of Prevacid®, and that it was neither defective nor unreasonably dangerous.

66. Plaintiff's claims are barred because Prevacid® was neither defective nor unreasonably dangerous in its design, manufacture or marketing and was reasonably safe and reasonably fit for their intended uses, thereby barring Plaintiff's recovery.

67. The warnings and instructions accompanying Prevacid® at the time of the occurrence or injuries alleged by Plaintiff were legally adequate warnings and instructions.

68. Plaintiff's claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the pervasive federal regulation of prescription drug manufacturing, testing, marketing, and labeling, and the FDA's specific determinations regarding Prevacid® and other drugs in its class.

69. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

70. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

71. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid in the United States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

72. Plaintiff cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiff is subject to the exclusive regulation of the FDA.

73. This Court should abstain from adjudicating Plaintiff's claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

74. All labeling for Prevacid® has been approved by the FDA under the applicable statute, 21 U.S.C. § 301 *et seq.*, and regulations promulgated thereunder. Plaintiff's claims are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution to the extent Plaintiff asserts that state law required changes to the FDA-approved labeling that the FDA itself would not have approved. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ____ (2019). Plaintiff's claims also are preempted by federal law pursuant to the Supremacy Clause of the United States Constitution because they would obstruct the federal regulation of drug labeling and frustrate the achievement of congressional objectives. Additionally, Plaintiff's design defect claims are barred by the doctrine of federal preemption under *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013).

75. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

76. Plaintiff's attempt to collect damages from Abbott based on Plaintiff's alleged injuries caused by a product that Abbott may not have manufactured or sold violates Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the applicable states' Constitutions, the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the applicable states' Constitutions.

77. Plaintiff did not suffer any actual injury, loss, or damages because of Plaintiff's alleged use of Prevacid®.

78. Plaintiff's claims may be barred, in whole or in part, because Abbott did not design, manufacture, promote, or sell the products which form the basis of Plaintiff's claims.

79. All or part of the injuries, damages, and/or losses, if any, sustained by Plaintiff, if proven, were caused in whole or in part by the acts or omissions of others for whose conduct Abbott is not responsible and/or resulted from conditions or events unrelated to any conduct by Abbott.

80. Some or all of Plaintiff's claims and/or damages, if any, may be barred, limited, or offset by the law of other states that may govern under this jurisdiction's choice of law provisions and resulting application of law from other jurisdictions. These may include, without limitation, another state's product liability statute, its applicable statute of limitations, its modified comparative fault doctrine, and limitations on the award of noneconomic and punitive damages.

81. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

82. To the extent that Plaintiff seeks punitive, exemplary, or aggravated damages ("punitive damages") for the conduct that allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Abbott's rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution(s).

83. Any claim by Plaintiff for punitive damages is in contravention of Abbott's rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; similar

provisions in the states of Plaintiff's citizenship; and/or the common law and public policies of such states.

84. To the extent that Plaintiff seeks punitive damages, said claim is unconstitutionally vague and/or overly broad because of the lack of clear standards. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitutions, and applicable state common law and public policies.

85. Plaintiff's claim for punitive damages against Abbott cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Abbott; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate

purposes on the basis of objective standards. Any such verdict would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under applicable state common law and public policies.

86. Unless Abbott's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of punitive damages would violate Abbott's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and the applicable state constitutions, and also would be improper under the applicable state common law and public policies.

87. To the extent that Plaintiff seeks punitive damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996) and subsequent cases, including *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346, 127 S. Ct. 1057 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008).

88. To the extent that Plaintiff seeks punitive damages, any award against Abbott on any grounds other than its conduct with regard to the product Plaintiff used would be improper under applicable constitutional principles.

89. No act or omission of Abbott was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiff or with conscious disregard and indifference to the rights, safety and welfare of Plaintiff and, therefore, Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

90. To the extent that Plaintiff seeks punitive damages, such claim is barred because the product at issue, and its labeling, was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

91. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Abbott and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the applicable state constitutions.

92. With respect to Plaintiff's demand for punitive or exemplary damages, Abbott specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and the applicable state law.

93. Plaintiff's Complaint seeks damages in excess of those permitted by law. Abbott asserts any statutory or judicial protection from punitive or exemplary damages which is available under the applicable law, including applicable statutory or other caps or limitations on the recovery or punitive or exemplary damages, and any award of punitive or exemplary damages is barred.

94. Each and every claim alleged or raised in the Complaint may be barred, in whole or in part, because Plaintiff may lack capacity or standing to bring the claims alleged.

95. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Abbott to determine all of its legal, contractual, and equitable rights, Abbott

reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent defenses ascertained through further investigation and discovery.

96. Plaintiff's claims against Abbott are barred and/or preempted by federal law because at no time did Abbott have authority to revise or modify the FDA-approved labeling for Prevacid®.

97. Plaintiff's claims against Abbott are barred in whole or in part because neither Abbott nor any subsidiary of Abbott was involved in the marketing or promoting of Prevacid® in the United States after 2003, and because in 2008, when Abbott Laboratories dissolved the TAP joint venture with Takeda, Takeda assumed the rights and obligations with respect to Prevacid®.

98. Discovery or investigation may reveal that some or all of the claims alleged by Plaintiff are barred by the doctrines of accord and satisfaction.

99. Abbott is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

100. Plaintiff's recovery as against Abbott should be barred in accordance with Ill. Comp. Stat. Ann. ch. 735, 5/2-621.

101. Plaintiff fails to state a claim for unlawful conduct under Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable "Deceptive Trade Practices Act," because Abbott completely complied with the applicable law in connection with the distribution of Prevacid®.

102. Plaintiff fails to state a claim for false or misleading business practices under Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable "Deceptive Trade Practices Act," because Abbott's sale of Prevacid® was not false or misleading.

103. Plaintiff's claims are barred in whole or in part because Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable "Deceptive Trade Practices Act," is insufficiently definite to provide adequate or fair notice of the conduct proscribed, in violation of the Due Process Clauses of the Fifth and Fourteenth Amendments to the United States Constitution and the due process protections of the Illinois Constitution.

104. Plaintiff's claims are barred in whole or in part because Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, or any other applicable "Deceptive Trade Practices Act," unconstitutionally burdens interstate business practices relating to prescription drugs, which are heavily regulated by the FDA.

105. Plaintiff fails to properly plead any claims under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, with sufficient particularity.

106. Plaintiff fails to state a cognizable claim under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, because the majority of the alleged violations of the Illinois Consumer Fraud and Deceptive Business Practices Act occurred outside of Illinois.

107. Plaintiff's claims asserted under the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq.*, are barred because Plaintiff does not allege proximate causation for Plaintiff's claimed injuries as required under Illinois law.

108. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable state's Uniform Commercial Code, Ill. Comp. Stat. Ann. ch. 810, 5/2-314, and/or other applicable law.

109. Abbott adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

110. Abbott is entitled to the benefit of all defenses and presumptions provided by the procedural and substantive law of applicable state and federal law.

JURY DEMAND

Abbott hereby demands a trial by jury by the maximum number of jurors permitted by law on all issues so triable.

PRAYER

WHEREFORE, having answered, Abbott requests that this Court enter judgment in its favor and against Plaintiff on all counts and allegations of the Complaint and that the Court award Abbott its costs and such other relief as it deems just and proper.

Dated: March 16, 2020

Respectfully submitted,

By: /s/ Sherry A. Knutson

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Attorneys for Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that a true and accurate copy of the foregoing was served on March 16, 2020 via electronic mail on the following:

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/s/ Sherry A. Knutson
Sherry A. Knutson

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

FILED
11/12/2020 7:44 PM
DOROTHY BROWN
CIRCUIT CLERK
COOK COUNTY, IL
2019L006045

JACQUELINE MEDIOUS-SANDERS,

Plaintiff,

v.

ABBOTT LABORATORIES, et al.,

Defendants.

Case No. 2019-L-006045

Calendar X

11123013

**STIPULATION OF VOLUNTARY DISMISSAL WITHOUT PREJUDICE AS TO
DEFENDANT ABBOTT LABORATORIES**

Pursuant to Section 5/2-1009(a) of the Illinois Code of Civil Procedure and the agreement of the parties, Plaintiff and all Defendants who have noticed their appearance, hereby stipulate and agree to the dismissal without prejudice of Defendant Abbott Laboratories, with each party to bear their own attorneys' fees and costs, and respectfully request that the Court enter the Stipulated Order. Other defendants remain in this action, and plaintiff will continue to pursue the action against the remaining defendants. Following the dismissal of defendant Abbott Laboratories, the parties consent to the removal of this action, and transfer to the United States District Court, District of New Jersey, IN RE: PROTON-PUMP INHIBITOR PRODUCTS LIABILITY LITIGATION (NO. II), MDL 2789 ("MDL").

Dated: November 12, 2020.

/s/ Brian J. Perkins

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Global Research & Development Center,
Inc.*

FILED DATE: 11/12/2020 7:44 PM 2019L006045

CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2020 I filed the above Stipulation of Dismissal without Prejudice as to Abbott Laboratories was served on All Counsel of Record via electronic mail to the addresses listed below.

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/s/ Sherry A. Knutson

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

JACQUELINE MEDIOUS-SANDERS,

Plaintiff,

v.

ABBOTT LABORATORIES, et al.,

Defendants.

)
)
) Case No. 2019-L-006045
) Consolidated Case No: 2019-L-
) 005876
)

) Calendar X
)
)

**PROPOSED AGREED ORDER OF VOLUNTARY DISMISSAL WITHOUT
PREJUDICE AS TO DEFENDANT ABBOTT LABORATORIES**

THIS CAUSE COMING TO BE HEARD on the Stipulation of the Parties to voluntarily dismiss Defendant Abbott Laboratories without prejudice, pursuant to Illinois Code of Civil Procedure, 735 ILCS 5/2-1009, due notice having been given, and the Court being fully advised in the premises:

IT IS HEREBY ORDERED:

- 4336
1. That Defendant Abbott Laboratories is hereby voluntarily dismissed without prejudice, pursuant to Illinois Code of Civil Procedure 735 ILCS 5/2-1009.
 2. Plaintiff has one year from entry of this Order to re-file, with costs upon refiling.
 3. The case remains pending against the following remaining Defendants:
Takeda Pharmaceuticals USA, Inc.; Takeda Pharmaceuticals America, Inc.; Takeda Development Center Americas, Inc. f/k/a Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited.

IT IS SO ORDERED this _____ day of _____, 2020.

Entered: _____


The Honorable Brendan A. O'Brien

Judge Brendan A. O'Brien

NOV 23 2020

Circuit Court - 2175